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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

HEARINGS

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

APRIL 29, MAY 20, AND JULY 30, 1987

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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Pesticide Contamination in Ground Water

WEDNESDAY, APRIL 29, 1987

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The committee met, pursuant to notice, at 9 a.m., in room 332, Russell Senate Office Building, Hon. Patrick J. Leahy (chairman of the committee) presiding.

Present or submitting a statement: Senators Leahy, Harkin, Lugar, and Bond.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

The CHAIRMAN. The committee will come to order.

I know that Dr. Moore has a time crunch because of commitments in another committee, so I'm going to place my own statement in the record. I would like to make a couple of points before we start.

Earlier this week I was in Vermont and I spoke to Vermonters about the problems of rural America and the need to protect the quality of life in our small towns. I described a six point plan for rural revitalization. Protection of the rural environment was an essential element of that plan. We cannot really do things to revitalize rural America unless we are protecting rural America's environment; and safe, clean drinking water is a basic American right.

That right is under attack. Half of Vermonters rely on ground water for their drinking water. I do at my own home in Vermont, and I want to be sure that Vermonters do not have their ground water poisoned by pesticides. We need to stop contamination before it reaches dangerous levels.

I think we have to do a better job of monitoring our drinking water so that we catch problems while they can still be prevented. We need a national ground water standard so that we know what levels are safe and what levels are dangerous.

States like my own and other States cannot do it alone. They need help from the Federal Government. They need strong national legislation. They deserve the right to go beyond the current Federal law to protect their citizens. Vermont needs technical assistance from EPA. For example, they need better information on how pesticides travel through soils and get into ground water.

Virtually every State in the Nation that we have heard from says the same thing. The current pesticide law simply does not do the job. I am looking forward to working with those who will testify today, and with others while trying to develop a better pesticide law for the American people.

[The prepared statement of Chairman Leahy follows:]

OPENING STATEMENT OF SENATOR PATRICK LEAHY
CHAIRMAN, SENATE COMMITTEE ON AGRICULTURE
OPENING HEARING ON GROUND WATER CONTAMINATION

Pesticide Contamination of Ground water: Assessing the Threat

Over 100 million Americans depend upon ground water for drinking water. In rural America there is almost total reliance on ground water--97% of rural residents drink, bathe and cook with ground water. Often, the water goes straight from the well--untreated--to the food that goes on the table.

There is no Federal law that protects ground water from chemical contamination. It is no wonder that ground water contamination is emerging as a major agricultural and environmental issue of the 1980's. Contamination of ground water by pesticides has become a critical issue for Federal and State government to resolve.

In my home State of Vermont 54%, or 275,000 people rely upon ground water as a source of drinking water. This is not some abstract hypothetical subject that we're talking about. This is one of the most basic necessities of life.

Until the late 1970's, pesticides were expected to degrade before reaching subsurface supplies of water. The contamination of ground water on Long Island in 1979 with aldicarb was a major--and tragic--discovery that the experts were wrong. Since then, aldicarb or Temik has shown up in numerous ground water samples in many States, such as Florida and Wisconsin.

Pesticide contamination can occur in a number of ways. Misuse in the management of pesticides, their manufacture and disposal are serious enforcement concerns. However, when pesticides are used as directed in normal agricultural practices, they can also leach into ground water. This normal use can create a problem as great or greater than misuse. EPA is beginning to classify categories of pesticides that are known or suspected "leachers" and to regulate them accordingly.

EPA has said that 17 pesticides have been detected in the ground water in 23 States as a result of normal agricultural use. Some experts say that the numbers are much higher and growing. The list is growing as the monitoring of pesticides in ground water increases. EPA and the States are grappling with a two-prong problem--how to prevent contamination and how to cope with it where it has occurred. Governmental agencies are also faced with the overwhelming task of notifying persons affected by contamination and providing health assessments of the risk posed for those who consume contaminated water.

This issue is a major concern for this committee and a major responsibility for this Congress. Ground water contamination is a nationwide problem that affects virtually every State. This is also a deeply personal concern that has already touched many families and many farm communities. With us today is a wife and mother whose family has been affected by this issue.

The Committee will be dealing with pesticides in ground water as a part of our effort to craft FIFRA legislation. This issue is as important as any issue in the legislation. The proposal included in last year's FIFRA reauthorization provides a constructive base for our work this year. I believe it is necessary, however, to assess the threat of ground water contamination from pesticides. Our witnesses today can shed some needed light on this subject.

The **Chairman**. Before we go to Dr. Moore, I will yield to my friend, the ranking member from Indiana, Senator Lugar.

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Senator **Lugar**. I thank you very much, Mr. Chairman.

I look forward to the hearings and the whole discussion of ground water and the problems we may have, and I suppose through an examination of the extent to which the EPA or those who are now charged with dealing with the potential contamination difficulties are able to do so, try to test the adequacy of their activities and programs.

I know in the course of these hearings we will hear suggestions for additional legislation, additional agencies, and we will need to weigh those carefully. I look forward to hearing informed testimony, and I join you, Mr. Chairman, in your enthusiasm for this project.

The **Chairman**. Our first witness is Dr. John Moore, who is the Assistant Administrator of the Office of Pesticides and Toxic Substances.

Doctor, would you please come forward?

We especially want to hear from Dr. Moore. There are over 100 million Americans who depend upon ground water for drinking water. In rural America, there is almost total reliance on ground water—97 percent of rural residents get their water direct from the well or the spring, and it goes into the pots with no purification.

So Doctor, it is all yours. Tell us what we are doing, what we should be doing, and what the problems are.

STATEMENT OF JOHN A. MOORE, DVM, ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Dr. **Moore**. Thank you, Senator. I would like to highlight some excerpts from my written testimony, and ask that the rest of the testimony be included for the record.

I am pleased to be here today to discuss the Agency's efforts to address the environmental concerns posed by pesticides, which may leach to ground water. In particular, I would like to highlight our progress in building a substantial knowledge base concerning potential leaching pesticides and the complex conditions under which pesticides leach. Then, I plan to outline for you the key features of our strategy for managing this environmental concern.

It comes as no revelation to the people in this room that back in the late 1970's we discovered, particularly with DBCP and aldicarb, that there were pesticides in some of our drinking water supplies, raising concerns that the problem may be associated with their leaching in to ground water. It soon became apparent that indeed, this contamination could occur through normal use of pesticides as opposed to some type of misuse of the chemical.

Today, as a result of increased State and Federal monitoring efforts, we are aware of a number of incidents where pesticides have been detected in wells around the country. These monitoring studies have been useful in identifying those chemicals that may leach and also in identifying those soil types and agricultural practices that may determine the probability of leaching at any one site. However, I think these studies cannot be aggregated to give us a representative national perspective on the general extent or degree to which pesticides are likely to be found in ground water. To fill this particular information need, the EPA has initiated a national survey of pesticides in drinking water wells.

The primary objective of EPA's survey is to establish the frequency and the concentration of pesticides in drinking water wells. It has also been designed to examine relationships between the presence of pesticides in wells and the vulnerability of ground water and the patterns of pesticide use in the surrounding areas. Using several newly developed multiresidue analytical techniques, EPA will examine a total of 1,500 public and private drinking water wells for the presence of some 70 priority pesticides and some 90 additional chemicals.

At the present time, we are in the pilot phase of the survey which is underway in Mississippi, California, and Minnesota; and if we find no hidden surprises in the results of the pilot phase, we will implement the full survey this fall.

While the results of the national survey will certainly enhance our basic understanding of the extent of pesticide occurrence in ground water, we will not be relying on the survey alone to answer all our questions. Over the last several years, I think we have built a substantial data base through the registration and reregistration requirements on potential leaching pesticides and on the use patterns and soil characteristics which favor leaching.

For all new pesticides that are coming on the market for outdoor use, EPA requires a full complement of environmental fate studies. We also have retrospectively required similar requirements for currently registered pesticides or previously registered pesticides, involving approximately 140 active ingredients.

If a pesticide is found to have a high leaching potential, the Agency looks carefully at its existing or proposed uses and determines what threat they may pose to ground water. When necessary, the agency can take a number of actions to mitigate a ground water threat, including labeling requirements, restricting use to certified applicators, or disallowing use or expansions of use if it is an existing chemical. In some instances, we have required registrants to conduct extensive field monitoring of ground water as a condition of registration.

In addition to requiring registrants to supply information, we continue to work closely with others, such as the U.S. Geological Survey, and with several States in order to build a significant information base. In particular, we have been investigating the potential for pesticides to reach ground water under the hydrogeological conditions of specific farming areas within this country, most notably the Midwest, the Southeast, and also the West.

As a result of these wide range of activities, I think we have a strong foundation to move ahead in building a long-term strategy for managing pesticide use in a way that will prevent or minimize the migration of these chemicals to ground water. In considering various approaches for our strategy, we actively sought the input of a diverse group of representatives within EPA and other Federal agencies; such as USDA and USGS; from States, industry, user, and environmental groups.

Today, I would like to share with you some of the key elements of our proposed strategy, which we hope to issue by the end of May.

Prevention, I think, is the key to our ground water strategy. Indeed, my remarks will focus almost totally on prevention; not to ignore incidents where contamination has occurred—they certainly need attention, but indeed I have found it difficult today for people to focus on the long-term key element, and that is to come up with a strategy to make sure these problems do not occur, rather than totally focus on, what are you going to do now that it has occurred in some instance.

I think the keystone of our strategy is a broad menu of protective measures that are available through FIFRA to manage a particular pesticide. Once a pesticide is identified as posing a potential threat to ground water, I think we need specific management plans to control the use of that chemical in a manner that will protect ground water. Such measures can include:

One, adjusting the rate and timing of the pesticide's application.

Two, restricting its use to certain areas or to certain crops.

And of course three, monitoring to ensure that the plan is indeed achieving its desired results.

These methods or these plans must be tailored to fit both the specific characteristics of the pesticide and the locations where the pesticide is used. I think another key element of the strategy is the concept of a reference point which can serve as an objective measure to evaluate the effectiveness of any plan. A reference point should be the concentration of the pesticide, that if found in ground water, would indicate that a management plan had not worked.

Under the Safe Drinking Water Act, EPA establishes Maximum Contaminant Levels (MCL's). When available, we intend to use the MCL as the point of reference. When such an MCL does not exist, the Agency will use standard risk assessment procedures to establish an interim reference point. In preparation for the national survey, which I mentioned a minute ago, we are completing the development of some 62 health advisories, which will provide these interim reference levels.

Reference levels can also be used as a basis of a scheme for gauging the progress of prevention efforts or early identification of possible concerns. This can be done by measuring pesticides in ground water, and then matching the levels found against the reference point that we want to make sure we never hit. Depending on the levels found in relation to the reference point, a management plan can call for consideration of a variety of activities. For example, if levels are some small percent of the reference point and begin to increase, management plans may have to be reassessed in a given locale and if necessary, revised. If that does not work and levels continue to increase, I think you need to get into more stringent type of response, which may involve restrictions of the pesticide's use in certain areas. However, because of the highly varied nature of the ground water resource including its vulnerability, use and value, these management plans must include prevention measures which are tailored to local situations if they are to be effective.

Which brings me to the most critical element of our strategy and that is the appropriate roles and responsibilities of the Federal and State governments. The basic policy of the Agency has been that States should have a dominant role in the management of their ground water resources, while the Federal Government should have the dominant role in identifying chemicals posing ground water concerns, setting basic standards for the States to meet, undertaking research and providing technical assistance to the States for effective management of the ground water resource.

Our proposed strategy would clearly extend this policy to the management of pesticides that have leaching potential. Our intent is to work with the States in development of these management plans, and when a State has the capability, it would have the primary responsibility for:

One, classifying its ground water according to vulnerability, use, and value;

Two, determining which measures are appropriate to protect drinking water supplies;

Three, responding to reports of pesticides in ground water and revising its management plans as appropriate;

Four, supporting an educational component that has a strong program for user training and enforcement; and

Five, in some cases, taking appropriate corrective action in those instances where something has gone awry.

The Agency's role is to identify those pesticides that pose a ground water concern and establish the levels of contamination that would serve as a reference point, if an MCL does not yet exist. The Agency may also require monitoring on the part of registrants to determine the effectiveness of a management plan. EPA would also keep abreast of reports from various parts of the country in order to establish national trends and provide information about one locale to sister States that may find it useful in dealing with their own circumstances.

Obviously, when there is a serious widespread problem, EPA should have a meaningful role at the national level; and perhaps impose either a national cancellation or a regional type of cancellation. However when a pesticide use poses a serious, but manageable local risk, it makes better sense for a State to tailor prevention measures that will remove the threat exactly where it exists.

Since 1985, the Agency has provided some $20 million in grants to the States to develop State ground water protection strategies. We hope to continue such support under our new programs, including the Wellhead Protection Program authorized under the recently passed Safe Drinking Water Act.

The CHAIRMAN. How much money has been set aside for that?

Dr. MOORE. I do not have the number. I would like to provide that.

The CHAIRMAN. Thank you.

[The following information was subsequently received by the committee:]

Once a State wellhead protection plan has been approved, the EPA Administrator may make a grant to the State to cover not less than 50 percent or more than 90 percent of the costs for developing and implementing the State plan. This funding authorization is limited to $20 million each fiscal year, FY87-FY88, and $35 million each fiscal year, FY89-FY91.

Dr. MOORE. When a State is unable to mount an effective management plan for a pesticide of concern, I think EPA will have to develop an alternate management plan for that State. An EPA-directed plan at best, I think, may be able to establish measures on a county-by-county level, and I think this is probably a crude attempt compared to what might be needed in some circumstances.

The better alternative is clearly a strong State role. Certain States, such as, Wisconsin, Iowa, California, and Florida, in my opinion, have already demonstrated their capability to address this issue.

As a matter of fact, I think that if EPA has to direct the management of a detailed technical plan from the banks of the Potomac a realistic Agency decision option may be to stop the use of the pesticide in a State that neglects to develop such plans.

In regard to legislative needs in general, I think FIFRA provides the broad reach that is needed to effectively implement the strategy that I have outlined. However, timely and efficient implementation of required management measures sometimes is problematic under the FIFRA statute.

As I have testified before, there are inherent delays built into under FIFRA in addressing certain activities. I think we need to have an ability to go forth with generic management rules based on levels of contamination in the context of the point of reference concept. We need that authority so that we do not have to do everything on a case-by-case basis.

Furthermore, I think that a meaningful State management plan must have the ability to be adaptive to the realities of what is happening in the implementation of that plan. I think you need to be able to make changes under real time circumstances. I am not sure that this will always be feasible with the inherent delays with FIFRA.

The CHAIRMAN. Do you revise pesticide tolerances for food for a given chemical detected in ground water?

Dr. MOORE. I think in most instances, we can. In most instances when we find pesticides in ground water and when it is a serious problem, we basically get into the mode of suspension for some of the uses, as happened with EDB and DBCP.

In summary, I think we have done a number of things that are key to pesticides and ground water management, but we need to continue to collect information about which pesticides leach and what conditions of use could lead to leaching. We also need to do a better job of disseminating that information to the people who have to make the decisions on a local basis.

We need to have a preventative perspective. And, we need to have a point of reference for gauging the success of our prevention plans. Obviously we need to tailor those plans to local circumstances. I think you need to get decisionmaking as close as possible to the issue in the field. That is where I think it becomes critical that we have a State presence, with a dominant role in some of this activity.

We need to have some objective means of monitoring success; and then furthermore I think we then need to go beyond the general statements that I have made this morning and develop the exact details of how we will implement the approach that I have outlined. I think there are a variety of ways that it can be done and there are several options that might be equally effective. I think we need to have a continuing dialog with the States in order to identify what they think might best work for their circumstances, and to the extent that it makes sense, allow some degree of flexibility by the State in the development of its plan.

I will be glad to answer any questions.

[The prepared statement of Dr. Moore follows:]

STATEMENT OF
JOHN A. MOORE
ASSISTANT ADMINISTRATOR FOR
PESTICIDES AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
UNITED STATES SENATE

APRIL 29, 1987

Good morning, Mr. Chairman and members of the Committee. I am pleased to be here today to discuss with you EPA's efforts to address the environmental concern posed by pesticides, which may leach to ground water. In particular, I plan to highlight our progress, over the last few years, in building a substantial knowledge base which identifies potential leaching pesticides and the complex conditions that may cause ground water to be vulnerable to leaching. I will then outline for you the key features of our strategy for managing this environmental concern.

BUILDING THE KNOWLEDGE BASE

Beginning in 1979, the discovery of DBCP and aldicarb in drinking water wells in several states throughout the country raised concerns about the potential problem of pesticides leaching to ground water. At first, it was thought that the contamination was a result of improper disposal, spills, or other unusual circumstances. However, it soon became apparent that the normal use of pesticides could impact the quality of underlying ground water. Following these initial findings, other pesticides, such as EDB and alachlor, were found in drinking water wells, further underscoring the potential problem of ground water vulnerability to pesticide use.

Today, as a result of increased state and federal monitoring efforts, we are aware of a number of incidents where pesticides have been detected in wells around the country. These monitoring studies have been very useful to EPA as well as the states in identifying chemicals of potential concern and in identifying some of the areas of the country with highly vulnerable ground waters. However, it should be recognized that because these studies are conducted independently within a state or county, they cannot be aggregated to give us a representative national perspective on the general extent or degree to which pesticides are likely to be found in ground water. To fill this particular information need, EPA has initiated a national survey of pesticides in drinking water wells.

The primary objective of EPA's National Survey of Pesticides in Water Wells is to establish the frequency and concentration of pesticides in drinking water wells throughout the country. The survey has also been designed to examine the relationship between the presence of pesticides in wells and the vulnerability of the ground water and the patterns of pesticide use in the surrounding areas. Using several newly developed multi-residue analytical methods, EPA will examine a total of 1500 public and private drinking water wells for the presence of 70 "priority" pesticides and 90 additional chemicals.

At the present time, the pilot phase of the survey is underway in the states of Mississippi, California and Minnesota, and preparations are underway to begin the full survey by this Fall. By 1990, we expect to have a statistically sound, comprehensive view of the extent of pesticide residues in public and private wells across the country.

While the results of the national survey will certainly enhance our basic understanding of the extent of pesticide occurrence in ground water, we are not relying on the survey alone to answer all our questions. Over the last several years, the Agency has built a substantial data base through registration/reregistration requirements on potential leaching pesticides and on the use patterns and soil characteristics which favor leaching. For all new pesticides coming on the market for outdoor use, EPA requires registrants to conduct a full complement of environmental fate studies, ranging from basic physical/chemical characteristics of pesticides to data on degradation pathways to soil studies in the field. For existing chemicals, EPA has required registrants to submit environmental fate data for approximately 140 pesticides. This information is identifying or confirming those pesticides that have a potential to leach.

When a pesticide is found to have a high leaching potential, the Agency looks carefully at its existing or proposed uses and determines if the use pattern will pose a potential threat to ground water. When necessary, the Agency can, and has, taken a number of actions to mitigate a potential ground water threat by a leaching pesticide, including labeling requirements, restricting use to certified applicators or disallowing the use of a new chemical or expansions of the use of an existing chemical. In some instances, EPA has required the registrant to conduct extensive field monitoring of ground water as a condition of registration.

In addition to requiring registrants to supply information, EPA continues to work closely with others, such as the U.S Geological Survey, and with several states to build a significant information base on pesticide use and its impact on ground water. In particular, we have been investigating the potential for pesticides to reach ground water under the hydrogeological conditions in specific farming areas of the country, such as the Midwest (Iowa, Kansas, Nebraska), the Southeast (Georgia, Florida), and the West (California's San Joaquin Valley). Complementing these monitoring efforts are a number of ground water research studies which EPA is conducting at several of its own laboratories and funding at several universities across the country.

AGRICULTURAL CHEMICALS IN GROUND WATER STRATEGY

The information base we have built as a result of these wide range of activities has provided us with a strong foundation to move ahead in building a long-term strategy for managing pesticide use in a way that will prevent or minimize the migration of these chemicals to ground water. In considering various approaches for the strategy, we actively sought the input of a diverse group of representatives from within the EPA and other federal agencies, including USDA and USGS, and from the states, industry, user and environmental groups. As a result, we are now in a position to put forth for consideration an overall framework or strategy to address this environmental concern. Today, I would like to share with you the key elements of our proposed Agricultural Chemicals in Ground Water Strategy.

The keystone to our strategy is the broad menu of protective measures available through FIFRA to manage a particular pesticide. Once a pesticide is identified as posing a potential threat to ground water, whether by its leaching characteristics or through monitoring information, a specific management plan can be established to control the use of that pesticide in a manner which will protect ground water. Certain measures which can be applied as part of a management plan include: (1) adjusting the rate and timing of the pesticide's application or the conditions under which it must be applied; (2) restricting the use of the pesticide to certified applicators, to certain areas or to certain crops; or (3) monitoring in some areas to ensure that the use of the pesticide does not significantly impact ground water. These measures must be tailored in a management plan to fit both the specific characteristics of the pesticide, including its leaching potential and toxicological properties, and the locations where the pesticide is used.

Another key element of our strategy is the concept of a reference point which can serve as an objective measure for evaluating the effectiveness of a management plan or, in some cases, determining the need for such a plan. The reference point would be the concentration of a pesticide that if found in ground water would indicate that a management plan was not working. Under the Safe Drinking Water Act, EPA establishes Maximum Contaminant Levels (MCL) as the standards that must be met by public drinking water systems. When available, EPA will use an MCL as the point of reference for determining if ground water is being adequately protected by a pesticide management plan. When an MCL does not exist, EPA will use standard risk assessment procedures to establish an interim reference point. In preparation for the National Survey, we are completing the development of 62 Health Advisories for pesticides which will provide these interim reference levels.

In addition to using the reference level as a means to assess the effectiveness of a management plan, it can be used as the basis for a system of graduated responses to increasing reports or levels of the pesticide in ground water. A management plan can call for the consideration of certain measures when a pesticide is detected in ground water at some percentage of the reference level. From the level of detection to some low percentage of the reference level, depending on the frequency of reports, the management plan may call for consideration of monitoring to determine the cause of the contamination and to determine if it is increasing. If levels begin to increase, the management plan may have to be reassessed and, if necessary, revised with local measures taken to prevent further contamination. If levels should continue to rise or are reported more frequently, a corresponding, more aggressive stance would have to be taken with perhaps broader areawide monioring requirements, changes in application rate/timing requirements, possible restriction of use to certified applicators, or in some cases, prevention of use in geographically vulnerable areas. If a reference level is exceeded, corrective, as well as registration, action would have to be promptly considered.

Because of the highly varied nature of the ground water resource in this country including its vulnerability, use and value, management plans must include prevention measures which are tailored to local situations if they are to be effective. In some farming areas, the soil and underlying hydrogeological conditions would protect valuable ground water from normal pesticide use. On the other hand, in certain areas of the country, the ground water may be very near the surface and the surface may be comprised of sandy soils, creating an ideal situation for pesticide leaching. This latter situation would create the highest level of concern if the ground water is serving as an important source of drinking water.

Perhaps the most critical element of our strategy is the appropriate roles and responsibilities of the federal government and the states. EPA's basic policy has been that the states should have a dominant role in the management of their ground water resource, while the Federal government should have a dominant role in identifying chemicals posing ground water concerns, setting basic standards for the states to meet, and undertaking research and providing technical support to the states for effectively managing sources of ground water contamination. Our proposed strategy would extend this policy to the management of pesticides.

Our intent, in the strategy, is to work with the states to establish and implement management plans for pesticides where they are needed. When a state has the capability, it would have primary responsibility for 1) classifying its ground water according to vulnerability, use and value; 2) determining the menu of measures necessary to protect drinking water supplies; 3) responding to reports of pesticides in ground water and revising its management plans, if necessary, to prevent further contamination; 4) supporting its management plans with strong programs for user training and enforcement; and in some cases 5) taking corrective actions to protect public health.

Under this state-managed approach, EPA's role would include identifying pesticides that pose a ground water concern and establishing the levels of contamination that would serve as the reference points for the state to use in deciding on appropriate measures to take in its pesticide management plans. On occasion, EPA may require monitoring to determine the effectiveness of a management plan in the context of the pesticide reference points. EPA would keep abreast of contamination reports and alert the states to national trends and provide technical assistance to a state when they must take corrective actions to protect public health.

Obviously, when a pesticide use poses a serious widespread ground water threat, EPA must take steps at the national level and, if necessary, impose a regional or even national cancellation on the use of the pesticide. However, when the pesticide use poses a serious, but localized risk, it makes better sense for a state to tailor prevention measures that will remove the threat exactly where it exists and thus, maintain on a national scale, the benefits that arise from the pesticide's use.

With a state-managed approach, the Agency would continue to support the states through its basic ground water programs. Since 1985, EPA has provided $20 million in grants to the states to develop state ground water protection strategies. The Agency hopes to continue such support under its new programs, including the new Wellhead Protection (WHP) program authorized under the Safe Drinking Water Act. The WHP program is providing the states with grants to delineate protection areas around public drinking water wells and to develop management programs to protect these wells from contamination. As such, the WHP can serve as an important tool for the development of state management plans for pesticides.

When a state is unable to mount an effective management plan for a pesticide of concern, EPA will have to develop an alternative management plan for that state. An EPA directed management plan, at best, may be able to establish measures on a county-by-county basis, but since the vulnerablity of ground water within any given county can vary greatly, parts of a county may not be protected adequately. In such a situation, EPA would have to rely heavily on the user to apply detailed label requirements and advisories to his particular farm site.

Obviously, the better alternative is a strong state role. As a matter of fact, certain states, such as Wisconsin, Iowa, California and Florida, have already demonstrated their capabilities in managing the pesticides in ground water concern. Some of the benefits that a state-managed approach would provide include: 1) better informed designations of the vulnerability, use and value of ground waters and where priority protection must occur; 2) a greater degree of tailoring prevention measures to specific local conditions;

3) more efficient labeling, education and enforcement efforts to support localized measures; and (4) clearer information to the user in the field. These advantages of a strong state-managed program with EPA oversight make the alternative of an EPA-directed management plan a second choice--an alternative used only when a state cannot establish an effective management plan. As a matter of fact, if EPA has to direct the management of a detailed technical plan, a realistic Agency decision option may be prevention of use.

LEGISLATIVE NEEDS

With regard to ground water legislative needs in general, I believe that FIFRA provides the broad reach that is needed to effectively implement our strategy. However, I would point out that our success will be dependent on timely and efficient implementation of required management measures. As I have testified before, there are inherent delays under FIFRA. As a result, some states may perceive that EPA is too slow, and they will try to go it alone. However, by themselves, many states will not be able to incur the substantial legal, scientific and political costs required to address this complex and emotional problem. This could result in needless delays in addressing the problem in many parts of the country.

CONCLUSION

In conclusion, I would like to emphasize that the Agency is committed to protecting the quality of the Nation's ground water resources and that we have taken a number of significant actions to demonstrate our commitment. During the last few years, we have built a substantial knowledge base and now can move forward with a management framework that will establish a strong federal/state partnership for implementing an aggressive and effective prevention effort. In developing our proposed course of action, we plan to work closely with USDA and other Federal agencies, and we look to this Committee for support in helping us address this public health and environmental concern.

THANK YOU.

The CHAIRMAN. I think one of the most important things is to figure out how to get the information out to the public. Sometimes we do studies and nobody knows about them. I remember the concern 2 or 3 years ago over the news story that finally uncovered the studies of water out in Fairfax County. It's an area where they certainly should have plenty of resources, yet they found out that the water—I do not know how anybody could justify drinking it—was full of chemicals. It was just frightening; yet apparently the authorities had known about it, and nobody else.

I want to know how much of the information obtained in surveys will be available to the public, and how will owners of a contaminated well, or people who are consumers of a contaminated public water supply know about the problem?

Sometimes if local or State governments know the water supply is contaminated they are not too eager to tell anybody about it. They sit there and say, "Well, we'll fix this up, but the election is in 3 months, and we really don't want anybody to know how we're falling down on the job." And maybe they have not fallen down on the job; maybe they have done everything they were supposed to, and your survey has revealed for the first time that pesticides have leached into the water. How do you get the word out? Unless you do, there will not be the kind of pressure needed to make changes.

Dr. MOORE. Senator, in response to the question of the States, I think basically we would like to give the State the opportunity to handle a contaminated well or such information first. That does not mean that we would just inform the State or the appropriate municipality and then say, "Our work is done."

I think we would like to give them an opportunity to first announce that, and the significance thereof.

The CHAIRMAN. I have no problem with that, and especially in Vermont I want to see the State being given that opportunity first; but let's say the State sits on it, or let's say the municipality sits on it. They don't get the word out. What happens then?

Dr. MOORE. Well, we are trying to develop within the Agency what is being referred to as the Electronic Bulletin Board. In essence, what we would like to see is that this type of information would be accessible. If we get this information, following quickly behind the notification of the State or locality of the presence of contamination, it basically would go into that data base along with any other type of information that one might have, as it relates to ground water.

The CHAIRMAN. How can an ordinary citizen get that information? I mean, can I hook up my home computer and say to my teenagers, "While you're getting all the things that your mother and father say you shouldn't be getting out of these various electronic bulletin boards, would you check on our ground water?"

Then they might say, "Sure, Dad. How about the keys to the car, too?" I want to know, is that enough?

Dr. MOORE. I don't think it is enough. I think that——

The CHAIRMAN. You see my point.

Dr. MOORE. Yes. I think information of that sort should be publicly available almost as it becomes known. On the other hand, I do think that an organization such as EPA or a State or local authority also has an obligation, when it announces the presence of chemical *x* at such a concentration in a given locale, to give some guidance as to what the significance of that may be.

Just the mere presence of a chemical, whether it is detected in a water supply, for example, does not necessarily mean or suggest that the world has come to an end. We may not like to have it there, but on the other hand I do think we should be able to give them some perspective as to what that number means in relation to an established health advisory, which I have mentioned earlier in relationship to reference levels, or MCL's as the need arises for all these types of chemicals.

The **CHAIRMAN**. How about a public file of where all contaminants have been found. Would you be willing to do that?

Dr. **MOORE**. I think so, but this electronic bulletin board would be an example of trying to make a "public file" at least electronically accessible to some people, other than just any file in the traditional sense of a piece of paper in some file.

The **CHAIRMAN**. So it would be possible for somebody in Burlington, Vermont or St. Louis, Missouri to call up and say "Do you have anything on our water supply, and if so, what does it say?"

Dr. **MOORE**. [Nods affirmatively.]

The **CHAIRMAN**. Are you getting the kind of information you need to regulate pesticides in ground water?

Dr. **MOORE**. I think in the main we are, Senator. I think a problem in ground water is that we are still all in a developmental phase. I think there is some degree of confidence on the part of a lot of people that they can predict which chemicals have the greatest potential to be a leacher, and they can identify those soil type or use pattern that may increase the likelihood of a chemical leaching.

I think what we are much less clever at, as a country or as a society, in being able to come up with an estimate of the actual quantities of material that will leach as a consequence of a given use. I think that is still problematic.

The **CHAIRMAN**. But you have to know what pesticides are used and for what crop and at what level they were applied. Do you have that information?

Dr. **MOORE**. Yes, sir.

The **CHAIRMAN**. Senator Bond.

STATEMENT OF HON. CHRISTOPHER S. "KIT" BOND, A U.S. SENATOR FROM MISSOURI

Senator **BOND**. Thank you, Mr. Chairman.

I apologize for not being here for the full testimony, because I am very interested in this subject, and Mr. Chairman, I thank you for holding hearings on this very significant matter. We are concerned in our State, as well, about contamination of ground water, even though many people in our State receive their primary drinking water from the rivers; and we have been frequently advised of the dangers of substances in surface water, but the ground water contamination problem is one which we view with a great deal of concern.

There are a couple points that I want to follow up on and again, I apologize if they were in your testimony I have not had a chance to review it yet. I appreciate your emphasis on providing some kind of advice as to the relative degree of danger in the contaminants found in ground water.

I have done some work in the past on public water supply systems and we are blessed with very accurate instrumentation now which enables us to find a little bit of harmful substance in almost everything. The real challenge these days, it seems to me as you indicated is, finding out what is really dangerous. There may be—part of the water we drink may have infinitesimal parts of things that would be harmful.

Do you have a system for prioritizing those things when you find ground water which is approaching the level where there may be some human health hazard? Granted, for the long term, we need to know where the pesticides or other contaminants are leaching into ground water. Do you have a prioritized system? Do you work with the CDC or other health agencies to identify levels at which a real potential for human health hazard exists?

Dr. **Moore**. Senator, we do not have any formal system working with an organization like CDC on these particular activities. What we have done is identified those 60 to 70 pesticides that we think represent those that either are known or have the potential to be leachers. This is in anticipation that a level of that pesticide may be found in some water supply either today, tomorrow, or in the future.

For the 60 or so chemicals, we have tried to develop a hazard advisory level or a reference level or an MCL, if it exists, under the Safe Drinking Water Act requirements. These levels are based on health concerns and would be that level at or above which there would be some degree of unacceptable risk.

We developed these levels internally, drawing upon the data base that is available through pesticide registration. We then subjected those to a peer review process. We are also trying to heavily involve some of the State health officials in the promulgation of these numbers so that they are comfortable with them as well. We hope that this early involvement will avoid a debate between EPA and some given State on whether or not it is the right level. We are trying to do this in a process that gets the States involved so that we are all comfortable with what that right number may be.

Senator **Bond**. I may say, Mr. Chairman, based on my experience, one of the greatest difficulties State governments have is in trying to resolve disputes when the Federal Government agencies cannot decide what is hazardous; and frankly I think this may be a disservice to be unable to give guidance as to what is a hazardous level, because if all contamination is treated the same, we may not be willing to take drastic action needed where there is a real and present threat.

I have to respectfully take a differing viewpoint from comments made earlier. I think if you get information that there is a contamination problem, number one, I think that the State and local governments are willing and in my experience have been most anxious to get that information out; and frankly the media.

If you tell them that this is a situation that presents a real health hazard, the media will monitor very closely and serve as a check on any State or local government which fails to get the information out. I think your challenge and the challenge of the Federal Government needs to be to help establish contamination standards, to advise people of the dangers, including the longrun dangers, and to prioritize those wells exhibiting levels of contamination which present a real health hazard.

I would urge you to pay attention particularly to that aspect. The other thing that I have heard suggested, and again I do not know if you have already touched on it or not, has there been consideration to requiring an identifying agent to be placed in pesticides? I understand there is a problem with identifying pesticides in drinking water, because you have to know what you are looking for before you can find it.

Have you thought about requiring some kind of fingerprint to be added to pesticides which might give you a more ready means of identifying when that contamination exists?

Dr. MOORE. Senator, that has not been brought to my attention for serious consideration. What we have just completed, as a prerequisite for the national survey, was the development, in most instances, of new methodologies that can allow one to screen water; broadly and if one can sense that a contaminant may be there, then go on to more precisely identify which chemical it is and at what level.

We have gone through a sensitivity testing phase for these 60-odd chemicals, and we are comfortable in our ability to detect them. In some instances, one might say that they would like to have lower limits of detection, but there is always an inevitable tradeoff when you are trying to have the ability to look for some 60 different chemicals in one sample. You run into the problems of not being able to detect certain chemicals if you use methods that are more highly sensitive for only a few chemicals.

I think we are reasonably comfortable with the current methodology we have. I think that the challenge is technology transfer of these methodologies to research institutions and to the State and local labs, as well.

Senator BOND. I notice that you did make some comments about the contamination, the relative impact of the contamination from agricultural pesticides versus other contaminants, and we have had problems in our State with contamination of drinking water from solid waste dumps, from radioactive materials, and the presence of radioactive contamination in drinking water.

Can you give us some assessment as to the role of agricultural pesticides in the overall problem of ground water contamination?

Dr. MOORE. Well, I think that is highly geographic. In certain areas of the country, I would guess that there may be a higher potential for chemicals to reach ground water because of certain agricultural practices. On the other hand, in the Northeast corridor, where there are heavy populations with heavy industry around them, the chemicals found there may well be a product of the industry, or domestic and urban use of chemicals; as opposed to agricultural uses.

The thing that sometimes I think transcends geography is probably some of the chlorinated solvents that are used by industry in a variety of circumstances, and are also used in pesticide formulations because they are the carrier solvents of one sort or another.

Some of these are also used in certain household products, such as drain cleaners.

But beyond chlorinated solvents, I think the answer to your question is, it all depends on what part of the country you are looking at.

Senator **Bond**. Now can you give us an example for an agricultural State, say, for example, in Vermont or Indiana or Missouri, just to take three——

The **Chairman**. Just off the top of your head.

Senator **Bond**. Yes. What the crop would be.

Dr. **Moore**. If I could switch to a different State.

Senator **Bond**. Pick one.

Dr. **Moore**. I have the results in front of me here of some work done by the State of Minnesota. The study identifies a number of chemicals that were looked for in some 500-odd wells in a series of samples done over the past 7 years. Approximately 38 percent of those 504 wells that were tested were tested positive for at least the presence of one pesticide.

Now, the levels that were found in most instances were far below these reference levels, the health advisory levels that we have established. Nonetheless, they were present.

What may occur in a survey such as this, and this is not a criticism of Minnesota or anybody else, is that when they are doing pesticide surveys, they are typically selecting the active ingredient pesticide to look for. They do not always look for the solvents or the inert materials that may also be part of that formulation, and often present in that formulation in far greater quantities than is the active ingredient.

I think we need to balance some of these surveys for pesticides along with surveys for some of the solvents or the carriers. Not all solvents but certainly some, we know, have a great potential to reach ground water.

Senator **Bond**. Thank you, Mr. Chairman.

The **Chairman**. Thank you, Senator Bond.

In answer to one of the questions Senator Bond asked you about the MCL's or maximum contaminant levels, I note in your prepared testimony that you say under the Safe Drinking Water Act, EPA establishes maximum contaminant levels, or MCL's, as the standards that must be met by public drinking water systems. When available, EPA will use an MCL as the point of reference for determining if ground water is being adequately protected by a pesticide management plan. When an MCL does not exist, EPA will use standard risk assessment procedures to establish an interim reference point.

Now looking at this as a layman, it would seem to me that if an MCL is reached, if a maximum contaminant level is reached, ground water danger already exists. Prevention has somehow failed. How do you use that as a point of reference? Does not that say that if an MCL is reached, the management has failed and a long term health risk is faced by the public?

Dr. **Moore**. Senator, I agree totally with your statement. In the context of a management plan, which is preventive in nature, if you use the MCL as your reference point, it also is your failure point in your management plan.

What I am saying is that we still need a point of reference. That is the point you want to make sure you never get to, in a prevention mode. What one wants to do is use that as a constant gauge to determine where you might be. I think in some instances, you do not want the chemical to get to the ground water.

I think you also need to be realistic. Given our great analytical capabilities to detect chemicals in water, we are going to find chemicals in water even at very low levels. I think when we find chemicals, we need to gauge their presence against an MCL, if it exists. If the level of the chemical is a thousand-fold less than the MCL, I think our concern and desire to manage the chemical may be different than if we found a 50 percent or two-fold difference from the MCL, which might suggest you had better get active pretty fast.

So it is our point of reference that we wish to use. When we are talking about correcting a situation where a level of contamination has occurred above the MCL; then the MCL then becomes a success level. When you can get a well back down to below the MCL, then it becomes drinking water again. But in the context of prevention, it is a failure point.

The CHAIRMAN. I do not want to overgeneralize, but would it be safe to say that a lot of people out in rural areas, with the healthful attitude that exists there, are being fooled as they turn on the water?

Dr. MOORE. Well, I do not know if they are being fooled. In a rural area, they are probably relying on their own well, and they may have no idea what might be in that water. It may be a concern, particularly in those areas of the country where we have very shallow wells.

The CHAIRMAN. Like my own.

Also to follow up on some of the things Senator Bond asked, I hope that you are developing the kind of procedures necessary to do a broader based test of water. I understand this is not the easiest thing to do; and obviously if you are going after a particular chemical, a PCB or something like that, you look for that and you can detect it.

But to the extent that you are able to develop, and have the resources to develop quick, simple, multiphase tests, the better, because that can also be shared with local or State laboratories. I know in my own State many, many people rely on shallow wells. That includes my own property. There needs to be a way to test it. You almost have to come in and say, "We'd like to test your water for such-and-such a thing." So you test it for that and say, "You're fine on that." Then you wonder about all the other chemicals you should have tested for, since the average person does not know what to ask for.

Certainly in this committee you will find a lot of support for any effort you would make to expand and develop these tests, and to make them as simple, inexpensive, and as available as possible to States and local communities.

Dr. MOORE. Senator, I think the problem is, while we have these methodologies for detecting the presence of some 70 or 100 chemicals for the survey, they are very expensive methodologies.

The CHAIRMAN. I understand.

Thank you very much. I know you have another commitment on the Hill, and I appreciate your being here.

Our next witness is Dr. George Hallberg. He is an environmental geologist from the Iowa Department of Natural Resources, a pioneer in the field of pesticide ground water contamination, and has conducted numerous ground water studies and surveys. He has also done research in other States in this field.

I am told that the Big Spring Basin Study, which he has headed, has provided a wealth of information in this crucial, but relatively new field of study.

Doctor, we are delighted to have you here. Senators from your State had told me of you. The floor is yours.

STATEMENT OF DR. GEORGE R. HALLBERG, SUPERVISOR, ENVIRONMENTAL GEOLOGY, IOWA DEPARTMENT OF NATURAL RESOURCES

Dr. Hallberg. Thank you, Senator. It is a pleasure to be here. With some of the introductory comments that have been made, I am going to just try to go briefly over a few high points and for your information and perusal, more detailed material is provided for the record.

Coming from an intensive agricultural State like Iowa, I would like to start with a preface: Over the past 20 or 30 years we have increased agricultural production; we have done so, really, in large part through the widespread utilization of agricultural chemicals. It is clear we increased our productivity, and have done so profitably, at least up to recent times.

On the other hand, this widespread, intensive, nonpoint source use, if you will, has had an adverse impact on water quality in many agricultural areas of the country and in the world.

Regarding questions you brought up about the extent of ground water contamination; there are indeed many ground water quality problems, but in an agricultural State like Iowa, for instance, both from our technical assessment as well as the public's perception, agriculture is our number one problem because it is so pervasive. Not perhaps in terms of acute concentrations in a particular water supply, but when we look at how pervasive the problem is around the State, it clearly becomes number one.

Just to make a few key points about these issues. One thing we do want to be very clear on is that we are finding pesticides leaching into ground water in many areas from their normal, routine use.

The often-cited EPA summary of 17 different pesticides found in ground water in 23 different States—that level of activity has changed quite drastically. That has already been updated to 22 pesticides, 24 States, et cetera, and some of the information I brought today will further amplify that.

Monitoring in Minnesota was mentioned; just briefly between Minnesota and Iowa, two States that have done some intensive monitoring, we found that over the full range of public and private water supplies in the past few years, somewhere between 33 to 38 percent of the mix of wells in the different situations that were sampled were showing pesticide residues. Nineteen different pesticides have been identified in ground water in these various studies, in these two States.

When we get into the rural area, especially in susceptible areas, we found in some of those regions that 70 to 90 percent of rural farm wells have contained pesticides. This is some thing that is no longer——

The CHAIRMAN. Doctor, would you please repeat that one?

Dr. HALLBERG. Well, I was mentioning figures about 19 different pesticides had been detected in studies in Iowa and Minnesota in ground water supplies over the past 2 years. From some extensive monitoring, constituting about 1,200 wells in the two States, both public and private water supplies.

The CHAIRMAN. And are those chemicals spread around? I mean, of the 19 different chemicals, would you just find one in a particular water supply or do you find several of them clumped in one water supply?

Dr. HALLBERG. They certainly occurred in different percentages. By far the most common thing we found is chemicals that have been in use for a long time in the Midwest such as atrazine. But some of them have been found in a small percentage of the samples. About 20 to 25 percent of all the wells that have had detections have had detections of multiple residues; more than one. The large majority of them tend to occur with elevated concentrations of nitrates, which becomes part of the overall and complicated concern when we begin to look at potential health risks and health factors.

In these assessments as well, I think we are also finding that perhaps point source problems and misuse problems may be more widespread than we would have liked to have thought, and these present us with a much more critical short term problem. These situations have much higher concentrations of residues.

These problems in agricultural States are so widespread it is difficult to talk about these as point sources. In States like Iowa and Illinois, for instance, we have many hundreds of ag chemical handling facilities around the countryside, with these potential problems.

Of course, the overall critical concern is with long-term chronic health implications. Very few of the pesticides—there are some—very few of the pesticides used today will likely reach acutely toxic poisonous level in ground water supplies. It is unreasonable for some of them to ever reach those kinds of concentrations; but there are indeed some legitimate concerns with the long-term chronic health effects.

Some States that have been involved in toxicological assessments have been working and setting their own standards, and some of the routine concentrations that we are seeing for some common pesticides in the Midwest are already at or exceeding proposed, health-based standards based on these chronic evaluations in States such as Wisconsin, for instance.

As was noted, such contamination at this time is most prevalent in the shallow part of the ground water system; but this is in part a function of time. We have not been using agricultural chemicals all that long; and this is true for just about any type of man-induced contamination; we are only seeing it in the shallow part of the ground water flow system.

But if such contaminants persist in the ground water system, which we are beginning to see evidence for with a variety of agricultural chemicals, it will indeed be transmitted to deeper ground water. So this has to be a consideration. Ground water contamination and protection is an important consideration.

The information is very clear for nitrates, for instance, where we have seen these rise concurrently over time with our widespread use of fertilizer. We have a limited data base on pesticides, but what we do have in both surface waters and ground waters, suggests that some pesticide residues are increasing, particularly, or at least in terms of their persistence, the amount of time we are seeing them there, if not in terms of concentration as well.

We have to make sure that we consider these nonpoint sources as we go down the road in terms of policy development and policy consideration.

You mentioned, Senator Bond, the use of surface waters, streams for drinking water. One of the things we have to keep in mind is that ground water and surface water are interrelated. We cannot cleanly separate them in the real world; and in part we see areas where the shallow ground water, for instance, may not be used for drinking water, but contaminants that get into it may in turn be delivered as the base flow into our streams that will end up as drinking water. So we have to keep a systems perspective, if you will.

From some of our studies in regard to surface water, we find that most current, public water-supply treatment programs are not removing the pesticides, and that is something to keep in mind as well.

Another aspect of policy goals that I think we need at times to reflect on is that we must clarify what we mean by ground water protection and drinking water protection. The two are different; they place burdens on different parts of society.

A better data base on pesticide usage must be developed. This is one of the things from the State's standpoint that we feel we must have. It is very difficult, at best, to construct monitoring and control programs when we do not have any real time or currently available data on pesticide use. This is considered privileged economic data, and we do not have it at this point. A number of States are moving on their own to construct data recording.

There is a serious need for independent research and work in these areas, and especially in the area of health and environmental epidemiological studies. The discussion with Dr. Moore focused on some of that. We need that information.

The **CHAIRMAN**. What do you mean by independent? Do you feel that the Federal Government has not been adequate?

Dr. **HALLBERG**. I am not saying that the Federal Government has not been adequate, but I would like to see more activity, say from groups like the National Institute for Environmental Health Sciences. The National Cancer Institute has been involved to some extent, but we need some larger scopes and broader perspectives. Much of the data that EPA relies on, of course, is supplied by industry, and while it may be good, the public confidence in it is not high.

We also need environmentally related population assessments, in the real world, besides laboratory assessments to base model judgements on.

Some of our concerns really grow out of epidemiological studies which, as I am sure you are aware, are not nice and clean; they do not provide firm answers, but they do provide us some insights, patterns of risk that we have to be aware of.

All of the problems I am talking about must be addressed through a more comprehensive approach to farm management. Our standard concerns in agriculture are for efficient crop production, soil conservation, and surface water protection, which has been the standard long-term needs. We must merge those, really, with the need to protect ground water as well, and this means some considerations that go into economic farm management.

One of the most interesting things I think that is coming out of some of the work in the Midwest comes out of opinion polls and surveys, sociological surveys of the farmers' attitudes. They make it very clear that the farmer, the farm family, are very concerned with these problems. In fact, 89 percent of farmers and farm families in surveys said they were very concerned about ground water issues, and that more needs to be done about it.

In that sense, too, it was very interesting that the polls came out with so many unexpected results; 65 percent of all farmers in similar surveys said they were in favor of tighter restrictions on pesticides; 52 percent, a majority, were even in favor of tighter restrictions on fertilizers.

Now, not that we are proposing those, but the thing is, the farmer is very cognizant of these issues; he is very concerned about these issues, and hence is very willing to work and make some adjustments. And this is very important, I think, in terms of how we approach the problem. No matter what we do in a regulatory sense, we cannot, and I do not think we want to regulate too much of what goes on at the farm, and we will have to rely on a variety of nonregulatory voluntary programs.

We have as someone called it, a "very teachful moment" here in the farm sector, because of their personal concern with these issues.

In this whole context I would leave one final note. That is, to fully resolve some of these problems, as well as other agricultural nonpoint source problems which must be considered such as soil erosion; we, really have to work, and I think we have to begin to integrate and balance our policies for production. Our commodities programs must be integrated with our policies for soil conservation and water quality if we are really going to deal with these issues in the long term.

In that regard, I do not want to overstate the concern and seriousness of the problem, but I do not want to understate it as well. In a State like Iowa or Minnesota, these are quickly becoming our number one concern, with ground water problems. And we must take steps to deal with it.

[Committee note: An article, "From Hoes to Herbicides—Agriculture and Groundwater Quality," by George R. Hallberg, printed in the Journal of Soil and Water Conservation, November–December 1985, Volume 41, Number 6 is held in the Committee file.]

[The prepared statement of Dr. George R. Hallberg follows:]

Summary Comments For The
United States Senate Committee On Agriculture
4/29/87

PESTICIDES IN GROUNDWATER

Dr. George R. Hallberg
Supervisor, Environmental Geology
Iowa Department of Natural Resources

The increased, widespread use of agricultural chemicals over the last 20 to 30 years, in response to policies to promote production, has profitably increased agricultural production (at least, until recently). However, it has also had an adverse impact on groundwater quality in many of the major agricultural areas of the United States and the world. The contamination of groundwater, related to nitrogen fertilizers (and nutrient management) and pesticides from routine use, as well as point sources has become a serious concern. The contamination of groundwater/drinking-water with toxic and hazardous substances, even in low concentrations, is of real concern because of the potential for long-term and widespread exposure to the public.

Research in various areas has clearly shown that the contamination of groundwater with nitrates has increased concurrent with the increased usage of nitrogen fertilizers. While many sources contribute nitrogen into the environment and into groundwater, synthetic fertilizers have become the major component in many areas, at current rates and methods of application. In rural states such as Iowa, South Dakota, and Kansas 20 to 30% of all rural wells exceed the RMCL for nitrate in drinking water. In susceptible areas, up to 70% of all wells in some counties exceed this standard. In Iowa, over 25% of the states population consumes water typically exceeding half the RMCL.

Pesticides are also occurring in groundwater with unanticipated frequency. The typical concentrations, from routine use, are in the 0.1 to 10.0 ug/l (micrograms per liter, or part per billion) range, which is typically well below acute toxic (poisonous) levels for most pesticides, but many are of concern for possible chronic (carcinogenic, teratogenic, immune-system dysfunction, etc.) effects. In part these occurrences from routine use are occurring because we did not fully understand the nature of water and chemical behavior, and movement through the soil.

Major Summary Points and Commentary

1. Some pesticides are clearly leaching to groundwater from their normal, routine use.

   - Overuse, illegal uses, spills, siphoning accidents, and point-sources all play a role in the growing problem, but they can not be the sole cause.

   - The widely cited EPA summary (Table 1) noting that 17 pesticides have been detected in 23 states is outdated, because of monitoring and research activities underway by various states and EPA.

- 19 pesticides (and some metabolites, in addition) have been detected in Iowa and Minnesota (see Table 2, and narrative), in the past few years. (See appendix for comment on other states.)

- Monitoring of water-supply wells in Iowa and Minnesota have shown 33% and 38% of all wells contain pesticides; 20-25% of those with detections exhibit multiple residues.

- In susceptible areas, 70-90% of rural farm wells have contained pesticides.

2. Point-source problems are also appearing to be widespread and are much more serious in the short-term because of the significantly higher concentrations of residues found in the groundwater (Table 2, for example).

   - When point-sources are considered 50 to 60 pesticidal compounds have been detected in groundwater.

   - Such local situations have caused the closing of a number of public-water supply wells in several states.

   - In intensively agricultural grain-belt states, such as Iowa, we have termed these quasi-point sources, because there are many hundred ag-chemical handling facilities and, hence, their effects may be more common.

3. Long-term, chronic health effects are the primary concern with pesticides in groundwater, from routine use. The concentrations of some common pesticides currently being detected, may already exceed some state's Preventive Action Levels, based on chronic toxicological evaluations (compare Table 2, with the Wisconsin summary data).

   - For many of the pesticides commonly occuring in groundwater it is unlikely that their concentrations could ever reach acutely toxic levels from routine use. Point and quasi-point sources are a different matter.

   - Iowa and Minnesota monitoring indicates that 20-25% of all detections show multiple pesticide residues; many areas show that residues tend to occur with elevated nitrate concentrations. This all complicates the health assessment and amplifies the general concern. Little is known about "inert" ingredients.

   - In Iowa it is already clear that over 25% of the states' population consumes water with pesticide residues, at least during part of the year.

4. Such contamination is currently most prevalent in the shallow portion of the groundwater flow system. This, in part, is a function of time. If such contaminants persist in the groundwater system, they will be transmitted to deeper groundwater.

   - While rural well construction can be a problem, the concerns of ag-chemicals in groundwater cannot/will not be resolved by requiring people to drill deeper wells. In some areas, these shallow groundwater sources have been the only economically available source of water for farm and rural residents.

5. Limited temporal data on pesticides in groundwater and surface waters suggest that some pesticide residues are persisting in groundwater, and that they are increasing, at least in terms of persistence, if not concentration as well.

   - This, obviously, has to occur to some degree. Modern pesticides obviously did not occur in groundwater prior to use.

   - Even as only persistence increases, the time-weighted exposure increases.

   - In an ongoing population-based study of 100 rural wells in Iowa, 11 different pesticides were detected in groundwater, in late February/early March, 9-11 months after general application.

6. Groundwater and surface water are inter-related; this must be realized in policy deliberations.

   - In humid regions, groundwater forms the baseflow of perennial streams and lakes; in arid areas, intermittent streams may recharge groundwater.

   - Hence, even where shallow groundwater is not used for drinking water, chemical contaminants that leach to groundwater may be delivered into surface waters, that in turn are used for drinking water.

   - Pesticide concentrations are typically greater in overland runoff into surface waters than in groundwater. Drinking water supplies using surface waters may be subject to common low pesticide concentrations derived from groundwater recharge, but also subject to short-duration periods of much greater concentrations related to runoff.

   - In karst areas, surface water may directly enter groundwater through "sinkholes," creating severe local problems. Some argue these areas are too limited to consider, but karst-carbonate aquifers underlie important agricultural areas throughout the eastern U.S.

7. Current public water-supply treatment programs are not removing most pesticide residues.

8. Policy goals MUST clarify if they are going to protect groundwater or drinking water.

   - While these are interrelated the goal clearly affects the nature of regulations and required activities and who bears the burden. Protecting groundwater puts the burden on the polluters, while protecting drinking water puts the burden, all the cost (and the risk) on the consumer.

   - Protecting groundwater, it would seem agreed, is a cost-effective way to protect drinking water.

   - If groundwater is not protected, future drinking water is jeopardized, particularly in rural areas.

9. A better data base on pesticide usage must be developed. It is difficult, at best, to construct monitoring and control programs with no publicly available data on pesticide use.

10. There is a serious need for independent health and environmental epidemiological studies, perhaps funded through the National Institute for Environmental Health Studies.

11. Public opinion polls and surveys of farmer's attitudes make it clear that farmer's and their families are very concerned with these problems and are willing to respond.

   - Surveys in Iowa show that 86% of the public, including 89% of farmers, consider groundwater contamination a serious problem; 83% of the public, 72% of farmers, said more needs to be done to solve these problems.

   - Various polls showed that anywhere from 77 to 84% favored 'tighter restrictions' on the use of ag-chemicals; 65% of farmers favored tighter restrictions on pesticides, and 52% of farmers even supported restrictions on fertilizer.

   - Attitude surveys show that the farm family is very personally concerned with their water quality, that they perceive the linkage between economic efficiency and contamination of groundwater, and that they are willing to adjust practices -- within reason.

   - These attitudes make this an ideal time for voluntary adoption for many beneficial agricultural-conservation programs.

   - A 1986 national Harris Poll found that 86% of the public said there should be no exceptions from meeting water-pollution standards.

12. These problems must be addressed through a more comprehensive approach to farm management. Standard concerns for efficient crop production, soil conservation, and surface water quality must be coupled with the need to protect groundwater, as well.

   - Integrated farm management is a neccessity, and also must be considered in economic assessments of pesticide restrictions and/or cancellations. It is ludicrous to assume that integrated management adjustments cannot be made to compensate for the loss of a particular product, in many cases.

13. To fully resolve these problems, as well as other agricultural nonpoint source problems, such as soil-erosion, policies for production (commodities programs) must be integrated with policies for soil conservation and water quality.

ADDITIONAL POINTS TO CONSIDER:

1. There are various generalizations that invariably get raised about these issues that deserve comment.

   - "It's only our new technology that allows us to detect these minute concentrations of chemicals..." While this may have been true when DDT was of concern, we have been able to detect parts per billion for over 20 years now; it is no longer "new" technology. We seldom analyzed groundwater for pesticides because we assumed they would not get there. Given the nature of such chemicals they demand detection.

   - It is commonly noted that many new pesticides are less toxic than aspirin. This is true for acute toxicities, for some pesticides. Many are far more toxic. As noted, however, for most compounds the concern with groundwater is NOT with acute effects, but rather with long-term, chronic effects. In this regard, aspirin is not considered wholly safe either (i.e., Reye's syndrome, in young people).

   - "With the modern advancements of this chemical age people are living longer, and most would concede, better than ever before..." True, and in large part, this is because of medical advancements and the food-nutritional improvements provided by modern agriculture. On the other hand, one of those modern advancements, that the rural community is generally well aware of, was the development of groundwater as a safe source of drinking water. Many of the epidemics of generations past (e.g., typhoid and cholera) were spread by contaminated water supplies. As people outlive the diseases of the past they have become concerned with things that may contribute to longer-term chronic health problems.

2. In the area of health concerns and risk assessment, it must be questioned if the contributions to exposure from food and water and other routes are adequately addressed. Have all food tolerance decisions considered exposure through drinking water? How can/will the issue of multiple residues in water and food be handled?

3. As alternative management practices -- the use of BMPs (Best Management Practices) -- have become a catch-phrase for ways to resolve these problems, we also need to ask:

   - What are these BMPs?
   - What are they best for?
   - How are they developed and established?
   - How do we get them accepted and adopted?
   - Is there any way to ensure their use and effectiveness?

   In this regard there is a clear need for: independently (government) supported research to prove-up BMPs environmentally, and economically; to get serious about applicator training and certification; to provide the needed support for the Cooperative Extension Service to carry out many aspects of the technology transfer. There always seems to be the assumption that Extension will take these good works to the countryside--to the farmer--yet their resources and staff are continually being cutback. Extension is still the entity most farmer's still trust.

4. The consideration of geographic restrictions, vulnerability mapping, site specific requirements, etc., have come to the fore as a compromise, or panacea to some, between continued unrestricted use and cancellation of products. At least two potential problems must be considered:

   - Many discussions of geographic restrictions seem to focus only on short-term considerations of whether or not the groundwater in an area is a current source of drinking water, but lose sight of the interactions of groundwater and surface water, for example. This issue again raises the focus of groundwater vs. drinking water protection.

   - There undoubtedly will be various inequities created by some scenarios: will the states apply restrictions and enforce them uniformly?; will farmers accept local inequities in use?, etc.

Table 1. Typical positive results of pesticide groundwater monitoring in the U.S., from routine use; from compilation by U.S.E.P.A. staff.

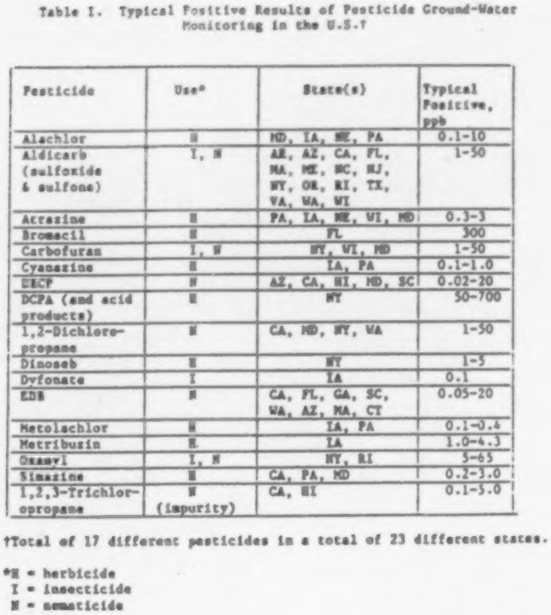

Table I. Typical Positive Results of Pesticide Ground-Water Monitoring in the U.S.†

Pesticide	Use*	State(s)	Typical Positive, ppb
Alachlor	H	MD, IA, NE, PA	0.1-10
Aldicarb (sulfoxide & sulfone)	I, N	AR, AZ, CA, FL, MA, ME, NC, NJ, NY, OR, RI, TX, VA, WA, WI	1-50
Atrazine	H	PA, IA, NE, WI, MD	0.3-3
Bromacil	H	FL	300
Carbofuran	I, N	NY, WI, MD	1-50
Cyanazine	H	IA, PA	0.1-1.0
DBCP	N	AZ, CA, HI, MD, SC	0.02-20
DCPA (and acid products)	H	NY	50-700
1,2-Dichloropropane	N	CA, MD, NY, WA	1-50
Dinoseb	H	NY	1-5
Dyfonate	I	IA	0.1
EDB	N	CA, FL, GA, SC, WA, AZ, MA, CT	0.05-20
Metolachlor	H	IA, PA	0.1-0.4
Metribuzin	H	IA	1.0-4.3
Oxamyl	I, N	NY, RI	5-65
Simazine	H	CA, PA, MD	0.2-3.0
1,2,3-Trichloropropane	N (impurity)	CA, HI	0.1-5.0

†Total of 17 different pesticides in a total of 23 different states.

*H = herbicide
I = insecticide
N = nematicide

Arkansas, Arizonia, California, Connecticut, Florida, Georgia, Hawaii, Iowa, Massachussets, Maine, Maryland, Nebraska, North Carolina, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, Washington, Wisconsin

From Cohen, S.Z., C. Eiden, and M.N. Lorber. 1986. Monitoring groundwater for pesticides. In, W.Y. Garner et al., [eds.] Evaluation of Pesticides in Groundwater. Am. Chem. Soc., Symp. Ser. 315, pp. 170-196. This listing includes only those detections which the authors, and their sources, would attibute to routine use.

IOWA AND MINNESOTA SUMMARY

There are many monitoring and research programs dealing with nitrates and pesticides in groundwater in Iowa and Minnesota ranging from statewide municipal water supply surveys to detailed research programs such as the Big Spring Basin Demonstration Program. A few highlights will be noted here.

Table 2 summarizes a variety of groundwater/well monitoring data from across Iowa and Minnesota, and some monitoring data specifically related to point source problems, in the vicinity of local farm chemical supply-formulation-rinse facilities. Exclusive of the point source data, these results are derived from over 700 wells in Iowa and over 500 in Minnesota. The results are remarkably similar, showing pesticide detections in 33% of all wells sampled in Iowa and 39% in Minnesota. In sum, 19 different pesticides have been detected. While not a true "statistical" sample, these wells are from a host of geologic environments of varying susceptibility. Clearly a picture is emerging from the consistency of the results.

It isn't always possible to prove that a particular residue in a particular well occurred from "routine use" and it will never be possible for every detection. Critics have suggested that many of the detections may result from "local hot spots," from small spills, dumping of left over formulations into road ditches, etc. If this is the case, the consistency of findings in Iowa and Minnesota, and other states, render these criticisms moot, because such conditions must be so common that they constitute "widespread and commonly recognized practices." (The pesticides with asterisks are known to occur from routine use, from monitoring in various detailed or controlled study areas.)

While this provides an overview a few other observations are worthy of note.

1. An ongoing, statistical population-based study in Iowa (sponsored, in part, by the Office of Pesticide Programs, U.S.E.P.A.) is sampling the wells of about 10 % of the active farmsteads in two counties (Floyd and Mitchell). The preliminary results from the first sampling 20 February-5 March, 1986, showed 40% of all wells (from different settings) contained residues of 11 different pesticides. The date of sampling illustrates the persistence of residues being seen.

2. Monitoring of private, farm wells in susceptible areas have shown 70 to over 90% of all wells with detections.

3. Public-water supplies using surface waters seasonally show higher concentrations, and multiple residues than typical groundwater sources.

4. Current water-treatment systems do not remove these contaminants.

5. Pesticide residues tend to occur in wells with elevated nitrate concentrations (Table 3), but the absence of significant nitrates does not mean that pesticides will not be present. In some environments nitrates are being naturally removed by denitrification but the pesticides have persisted.

Table 2. Summary of pesticides detected in groundwater supplies in Iowa and Minnesota, (from Hallberg, 1986, 1987; Klaseus, 1987; Kelley et al., 1986). N.D. = not detected. Total Water-Supply wells with detections, approximately: 33% - Iowa, 38% - Minnesota; 20-25% of wells with detections show multiple residues.

Common Name Active Ingredient	Maximum Concentration µg/l Iowa/Minnesota	Percent of Detections % Iowa/Minnesota	Maximum Concentrations from known Point Sources - Iowa µg/l
Herbicides			
*alachlor	16.6 (250.)/9.8	15/11	580.0
*atrazine	21.1/42.4	72/72	600.0
chloramben	1.7/N.D.	<1/0	
*cyanazine	13.0/0.10	12/1	36.0
*dicamba	2.3/2.1	2/2	
*metolochlor	12.2 (14.0)/2.1	10/2	250.0
*metribuzin	6.8/0.78	9/2	28.0
picloram	N.D./0.13	0/1	
propachlor	1.7/0.52	1/3	
simazine	N.D./2.6	0/<1	
*trifluralin	0.2/N.D.	1/0	0.2
*2,4-D	0.2/4.2	<1/2	
2,4,5-TP	N.D./0.26	0/1	
Insecticides (and nematicides)			
aldicarb	N.D./30.6	0/<1	
carbofuran	0.06/N.D.	2/0	0.2
chlorpyrifos	0.07/0.21	<1/2	
*fonofos	0.90/N.D.	1/0	1.3
phorate	0.10/N.D.	<1/0	
terbufos	12.0/0.63	2/<1	
Fumigants			
EDB			1.0
1,2,DCE			2.0
Carbon Tet			66.0
Chloroform			4.0
Nutrients			mg/l
Nitrate-N			20-117
Ammonia-N			290
Potassium (K)			510

(Max. in parenthesis from local karst setting, drinking water wells.)
* Some known occurrences from routine use.

Table 3. Summary of pesticide detections in groundwater in relation to nitrate (NO_3) concentrations (mg/l) in the sample from February-March, 1986, sampling Iowa 'population-based' study.

NO_3 NO_3-N	<5 <1	6-22 1-4.9	23-44 4.9-9.8	>45 >10
No. Wells in NO_3 class	83	27	39	29
%	47%	15%	22%	16%
No. with Pesticides	16	13	23	21
%	19%	48%	59%	72%

-Hallberg, G.R., 1986. Overview of agricultural chemicals in ground water. Agricultural Impacts on Ground Water. Nat'l. Water Well Assoc., Worthington, OH 43085, pp. 1-63.

-Hallberg, G.R., Libra, R.D., Long, K.R., and Splinter, R.C., 1987. Pesticides, groundwater, and rural drinking water quality in Iowa: In, Pesticides and Groundwater: A Health Concern for the Midwest, pp. 83-104. The Freshwater Foundation and the USEPA, Navarre, Minn.

-Klaseus, T., 1987. Minnesota pesticide monitoring surveys, interim report. In: Pesticides and Groundwater: A Health Concernm for the Midwest, pp. 137-158. The Freshwater Foundation and the USEPA, Narvarre, Minn.

-Kelley, R., Hallberg, G.., Johnson, L., Libra, R.., Thompson, C., Splinter, R., and DeTroy M., 1986. Pesticides in ground water in Iowa. Agriculture Impacts on Groundwater. Nat'l. Water Well Assoc., Worthington, OH 43085, pp. 622-647.

-Kelly, R.D.: Pesticides in Iowa's drinking water. In: Pesticides and Groundwater: A Health Concern for the Midwest, pp. 115-135. The Freshwater Foundation adn the USEPA, Navarre, Minn., 1987.

CALIFORNIA

In a total compilation of point and non-point sources, over 50 pesticides compounds have been detected in groundwater in California, from various levels of monitoring.

-Holden, Patrick, 1986. Pesticides and groundwater quality: issues and problems in four states. Nat'l. Acad. Press, Nat'l. Research Council, Bd. on Agric., Washington, D.C., 124 p.

During 1984 and 1985, California Dept. of Health Services conducted a sampling of 819 large public water systems. A total of 2,947 wells were sampled; 18.3% had organic chemical contaminants, mostly industrial chemicals; over 40% of the contaminated wells were in Los Angeles County. Even in these large public water supplies four pesticides were detected.

Pesticide Detected	% of all Wells Sampled	% of Contaminated Wells
DBCP	5%	29%
atrazine	1%	7%
simazine	<1%	5%
1,2-DCP	<1%	<1%

-"Final Report On a Monitoring Program For Organic Chemical Contamination of Large Public Water Systems in California," California Dept. of Health Services, April 1986.

In the compilation of a database on pesticide occurrences in wells/groundwater strictly from non-point sources, the California Dept. of Food and Agriculture assessed records on over 5,000 wells from 26 counties. Detections of residues of 11 pesticides (out of 34 analyzed for) were noted, 5 of which were verified to be from routine, or non-point source use; 67% of the detections were for DBCP. The residues detected included:

Those confirmed as originating from routine agricultural use;
DBCP, EDB, 1,2-DCP, simazine, and aldicarb.

Those from undetermined sources;
carbofuran, chloroform, lindane, D-D mix, PCP, and endrin.

-Cardozo, C.L., et al., 1985. Agricultural pesticide residues in California well water: development and summary of a well inventory data base for non-point sources. Calif. Dept. of Food and Agric. (July, 1985), 65 p.

KANSAS

The Kansas Dept. of Health and Environment sponsored a random statistical survey of rural farmstead wells; 104 wells were sampled (of an estimated 40,000). Of these, 28% exceeded the nitrate MCL, and 7% showed

detections of alachlor, atrazine, chlordane, heptachlor epoxide, tordon, 2,4-D, and 2,4,5-T.

Pesticide detections approximated 15% in eastern Kansas.

-Steichen, J., et al., 1986, Kansas Farmstead well survey for contaminants by pesticides and volatile organics. In: Agricultural Impacts on Ground Water, Nat.l Water Well Assoc., p. 530-541.

Kansas has also monitored surface waters/streams and lakes for pesticides as part of the Kansas Ambient Stream Water Quality Network. In the Kansas Network stream samples were analyzed for pesticides from 100 to 120 sites throughout the state, but only semi-annually or annually. Also, in contrast to Iowa, there are much greater differences in the intensity of agriculture and pesticide use across Kansas. Even with these differences similar trends are apparent. For the 1977 to 1984, period of record, total detections increased from 11% in 1977 to 72-78% in 1983 and 1984. Since 1977, 21 different pesticides have been detected, with a yearly low of 5 (1977) and a high of 17 (1983). Five pesticides (atrazine, alachlor, metolachlor, 2,4-D, and metribuzin) have accounted for 77% of the total detections. Atrazine has always been the most frequently found pesticide. In total frequency of detection atrazine equalled 40%, alachlor 12%, metolachlor 10%, 2,4-D 9%, and metribuzin 6%. Similar overall trends were noted for lake monitoring, as well.

Butler and Arruda (1985) note that clear patterns in the geographic locations of detections are routinely found. Eastern Kansas streams and lakes show the most consistent pattern of detections, likely related to greater pesticide use and higher runoff conditions. They also found pesticides in treated drinking water.

-Butler, Michael K., and Arruda, Joseph A., 1985, Pesticide monitoring in Kansas surface waters: 1973-1984: Perspectives on Nonpoint Source Pollution, USEPA, EPA 440/5 95-001, Wash., D.C., p. 196-200.

MAINE

The Maine Geological Survey, in 1985, conducted a limited sampling of 47 wells, in response to concerns with aldicarb and high nitrates in wells in some agricultural areas. They detected: NO_3-N, greater than the RMCL in 26% of wells; and low concentrations of dinoseb (11%), metribuzin (6%) thiodon (2%) atrazine (?), alachlor (?), and hexazinone (4%). (Percentages of wells where pesticides were detected given where known.) From Maine Geol. Survey, Dept. of Conservation, 1986, "1985: The Year in Review, Activities of the Maine Geological Survey, Dept. of Conserv.," 10 p.

MINNESOTA

(See Iowa-Minnesota Summary table, also.)

Limited (1984) sampling of rural domestic water supply wells, in the "Garvin Brook Project," Rural Clean Water Program, has detected alachlor and atrazine from routine use.

NEBRASKA

In 1985, the Nebraska Department of Health conducted a statistical survey of 447 rural farm wells in 21 counties in Central Nebraska. The area was divided into 3 'strata' or groups based on susceptibility to contamination for soil and geologic conditions; with increasing susceptibility from stratum I to III.

	% of Wells (No.) in excess of 10 mg/l NO_3-N (RMCL)	% Wells (No.) With 1 or more Pesticide Detected
Stratum I	0.8% (1/126)	0.0% (0/126)
Stratum II	8% (11/135)	3% (4/135)
Stratum III	14% (26/190)	8% (15/190)

Pesticides Detected	% of Detections
atrazine	81% (17/19)
alachlor	5% (1/19)
cyanazine	5% (1/19)
fonofos	5% (1/19)
trifluralin	5% (1/19)

- 32% of wells with $\geq$ 10 mg/l NO_3-N also showed pesticide detections

-"Domestic Well Water Sampling in Central Nebraska: Laboratory Findings and Their Implications.: Nebraska Department of Health, 1985, 16 p. plus appendices, mimeo report.

[Prior studies have detected atrazine and to a limited extent, alachlor from routine use; in some counties over 70% of wells sampled exceed 10 mg/l, NO_3-N.]

OREGON

A study in an agricultural area around Ontario, Oregon has found widespread contamination of a shallow aquifer, with NO_3-N and DCPA, from routine use.

-Bruck, G.R., 1986. Pesticide and nitrate contamination of ground water near Ontario, Oregon. In: Agricultural Impacts on Ground Water, Nat'l. Water Well Assoc., p. 597-612.

PENNSYLVANIA

Monitoring in relation to the "Conestoga Headwaters Project" Rural Clean Water Program, and other controlled watersheds (Pionke, et al., 1986) have detected

atrazine, simazine, alachlor, and metolachlor

in groundwater related to routine use.

-Pionke, H.B. et al., 1986. Pesticide contamination of groundwater in a rural Pennsylvanian watershed. In: Agricultural Impacts on Groundwater, Nat'l. Water Well Assoc., p. 542-563.

SOUTH DAKOTA

Limited area studies; sampling from monitoring wells and some domestic water supply wells, from "Oakwood Lakes-Poinsett Project; Rural Clean Water Program (RCWP) has detected (in order of frequency)

alachlor, 2,4-D, metribuzin, atrazine, and trifluralin

presumably from routine use. Alachlor in approximately 10% of samples. Notes peak concentration in April (1985), 10 months after last application, 2 months prior to new application.

WISCONSIN

The following table summarizes some of the available data from Wisconsin from both point sources and routine use.

Pesticide	% of Wells Samples with Detections	Maximum Concentration µg/l	Current PAL* µg/l	Proposed PAL µg/l
alachlor	7%	3000	--	0.015
aldicarb (total, including metabolites)	25%	111.0	2.0	<1.0
atrazine	16%	1500.0	--	0.035
butylate	20%	4.9	--	40.0
carbaryl	2%	45.0	--	--
carbofuran	<1%	15.0	10.0	--
chloramben	2%	50.0	--	--
copper (Tot, Cu)	20%	110.0	500.0	--
cyanazine	10%	130.0	--	1.0
DCPA (only 8 wells)	25%	760.0	--	--
dicamba	10%	320.0	--	--
dimethoate	5%	1.5	--	--
dinoseb	3%	2100.0	2.6	--
EDP	25%	12.0	0.001	--
EPTC	4%	2.9	--	10.0
lead (tot, Pb)	33%	3300.0	5.0	--
metolachlor	14%	440.0	--	1.5
metribuzin	9%	940.0	--	--
simazine	24%	15.0	0.43	--
2,4-D	2%	100.0	20.0	--

* Wisconsin Preventive Action Limit.

-Kessler, K., 1987. Wisconsin's groundwater monitoring program for pesticides. In: Pesticides and Groundwater: A Health Concern for the Midwest, The Freshwater Foundation and U.S.E.P.A., p. 105-113.

-Anderson, H.A., Belluck, D.A., Sinha, S.K. Recommended public health related groundwater standards - 1986; Summary of scientific support documentation for NR 140.10, Wisc. Div. of Health, Dept. of Health and Social Serv.

OTHER STATES

Monitoring has begun in a number of other states as well. Various technical publications which record pesticide residues from stream base flow and tile drainage provide indications of other pesticides and/or states where residues will likely be detected in shallow groundwater; e.g., tile-line effluent studies from Indiana, Michigan, and Ohio suggest that atrazine, alachlor, and carbofuran may leach to shallow groundwater in these areas.

The **Chairman**. You know, Doctor, I am not surprised to hear the result of the survey showing that the people of rural areas are very concerned about these matters, and far more concerned than the press sometimes gives them credit for. After all, they are the ones most directly affected by it.

Did you find it at all surprising that they were willing, in effect, to consider restrictions, restrictions that may have caused them some economic detriment?

Dr. **Hallberg**. Well, that is one of the interesting things that was in the poll. We were not surprised that they were willing to make adjustments, because the farmers clearly perceive the economic linkage between chemical loss and dollars that are spent in production.

With most polls that have been run, two things have fallen out: Number one, they do not like the sight of regulation, period. You know, a good 30 to 40 percent say no on that; "I don't want to see any kind of restriction of my activities, even if I don't do that, I don't want to see that happen."

But there is much greater willingness here to see that. In fact, if you look at some of the data, farmers are very concerned about their personal safety in the handling of pesticides. Read the farm journals and the newspaper, and see some of those patterns of risk we are talking about, and many of them do not like to handle chemicals.

The **Chairman**. There is also the desire for longevity; they know they are going to have to live for 150 years just to get the farm out of debt.

Doctor, we asked Dr. Moore whether EPA has adequate pesticide use data. I asked him whether they knew where it is being used and in what quantities. He seemed to indicate that they did have adequate use data. Do you think they do?

Dr. **Hallberg**. Not really. I think maybe on a national perspective. Of course, they have some data that is not readily available; it's in the safe because some of it is classified as confidential.

At the State level, for instance, as he was saying, where sometimes these decisions are going to have to be made, we would like to have information, data on a county level or even smaller so that we know for sure what is being used when and where. We have a bill in the Iowa legislature right now that would require annual reporting of sales records so that we can track that in some of our programs.

The **Chairman**. Doctor, with recurring use patterns of pesticides, are we likely to see greater ground water contamination?

Dr. **Hallberg**. Well, the way things have been going up until recently, yes, indeed; we seem to be seeing increasing quantities—well, at least in terms of their persistence, if not in terms of concentration in ground water systems.

We have some data that goes back 10 or 15 years, where we have only seen intermittent detection; and now we see some in water supplies constantly, year round.

Ground water is kind of like a conveyor belt, if you will. Once we put something on to the conveyor, it is going to be moving along for some time before it falls off at the other end, even if we stopped up here today, some of what is in the system is probably going to make it there.

The Chairman. If you did prohibit a particular chemical or at least prohibit the amount which is being used, that does not guarantee that the next day all is fine——

Dr. Hallberg. No.

The Chairman [continuing]. Chemicals can be traced for a long time; is that correct?

Dr. Hallberg. That is part of the whole problem with ground water. There is a lot of temporal, long term concerns that have to be brought into the fray. You know, if you shut off a point source dumping into a stream, you shut it off and it's going to dissipate fairly quickly as it moves down stream; but ground water is a much slower-acting system, and it will be some time before we see the responses.

The Chairman. From the national perspective, is this a bit of a problem, an interesting problem, or a truly serious problem? How would you categorize it?

Dr. Hallberg. The agricultural portions of ground water contamination, again, as Dr. Moore said, you have got to look at it geographically, obviously, but I think in some of the farm States in particular, especially the grain producing States, the Corn Belt, the Mississippi River belt—I think it is a very serious problem. That is from an assessment of what we have found where we have looked for both industrial chemicals and farm chemicals.

It is a situation, I guess I can characterize it as, certainly not one for panic; but the concentrations of nitrates in some areas are at very high levels, and we have to be very concerned about them.

The Chairman. But how do you reduce the nitrates? And the use or overuse of fertilizers? How do you reduce that?

Dr. Hallberg. What we are shooting at right now I guess is a very aggressive statewide program with farmers on better management. We really find that there has been a fair amount of overuse; not intentionally by any means, because in part we did not understand how inefficient some of our system was.

We find that with the rates of fertilization that we are using now, even when we try to do the best job, we may only be recovering 40 percent of the fertilizer, nitrogen we paid for, in the grain where we want it to go.

There are many other sources of nitrogen that we have not taken advantage of, that contribute, in terms of rotation effects. There are steps we can take with just better management, that we know we can reduce the losses about.

The other aspect of it is——

The Chairman. You are not saying nitrates should stop being used; you are just saying they can be used effectively to a lesser degree.

Dr. Hallberg. More efficiently.

The Chairman. Thank you.

Dr. Hallberg. We think we have really made some major steps with fertilizers, just in terms of efficiency. Pesticides are a little tougher, in part because we do not understand them as well as we do nitrates in the environment.

The CHAIRMAN. We have also been joined today by Senator Durenberger from Minnesota. He has a great deal of expertise and interest in the subject of ground water.

Do not leave, Doctor; you are still on. We want to give Senator Bond and the distinguished Senator from Iowa a shot at you. I want you to know that you have been doing Iowa proud so far here this morning; but I just wanted to note that Senator Durenberger has arrived. I am delighted to have him participate in the hearing, because while on another committee he has developed a great expertise in this. He has been among those who have constantly kept to the forefront of the ground water concern.

I am glad to have you here, Dave.

Senator DURENBERGER. Mr. Chairman, thank you very much.

I know how you feel, from the time I have spent with you, about the State you represent, but it is very impressive to see the State flag up there on the wall.

The CHAIRMAN. I want you to know, on the first meeting of the Agriculture Committee this year, Senator Heflin from Alabama wondered why the Vermont flag was up there in place of the tobacco leaves that had been there for so long before. That was only because we felt that the former chairman, who had been so generous to loan us the tobacco leaves for the past 6 years might want them back. And the Vermont flag went up there; and I pointed out that the Vermont flag was flown by me over the South Pole, coldest place on earth. Senator Heflin commented that, it being a Vermont flag, it probably felt right at home.

We then switched on to other subjects. But it does have that agricultural motif.

STATEMENT OF HON. DAVID DURENBERGER, A U.S. SENATOR FROM MINNESOTA

Senator DURENBERGER. Mr. Chairman, I want to begin by thanking you for the opportunity to participate in this hearing. I feel right at home here, too, in this environment, because you, last year as we got ready to go to the floor on the FIFRA bill, and we were in either phase 5, 6, or 7 of a series of our hearings on ground water, it was you who led off that stage of our hearings over in Environment and Public Works that dealt with the effect of pesticides in ground water.

You were the lead witness at that hearing. So you were extremely helpful, to our thinking, on Environment and Public Works. You personally, and I hope that I can be somewhat as helpful in your work this year.

I am not an expert on the ground water resource or the adverse health and environmental effects that ground water contaminants may cause. I have no training in toxicology or epidemiology or hydrogeology. I think we all know that ground water is a very complex subject that we lawyers need a lot of remedial scientific education just to muddle our way through.

But I do consider myself a bit of an expert on ground water legislation. I got my education the old-fashioned way as they say. I earned it. When the FIFRA amendments came out of this committee last year, I took on three issues which caused me special concern: ground water, food residues, and liability. You recall I went to the floor with the amendments, amendments which I had to defend right up to the final hours of the 99th Congress. So I think I understand the politics of FIFRA and ground water. And based on that experience I am here this morning to urge you to press ahead with the legislative effort.

There is no doubt that pesticide contamination of ground water is a high national priority. Iowa and Minnesota are the proverbial tip of the national iceberg, but you do not have to go very far to get to the rest of the problem. As you begin work on the pesticide law, your first day of hearings is on ground water contamination rather than food residues or worker safety or data gaps or any number of other issues. When I come at it from the other side, from the general ground water perspective over in the Environment Committee where all sources of contamination—from Superfund sites to septic tanks are up for consideration—I find that the first priority of concern is pesticides in the environment.

If one were to list the States with aggressive ground water protection programs—Wisconsin, Florida, New York and perhaps Iowa in the near future—one would find that it was pesticide contamination that first brought the ground water problem to public attention in each case. Pesticides are at the heart of the current national debate on ground water protection.

So, this is an important subject that is worthy of your efforts. The second point I would like to make is that a legislative vehicle to address the problem is at hand. Last year, both the House and the Senate passed FIFRA bills that contained ground water protection amendments. This amendment had been developed first through the NACA-CPR negotiations, and then in consultation with EPA, and finally with a lot of consultation among Members of the House and Senate directly. There was not a great deal of difference between the House and the Senate ground water provisions when the 99th Congress closed its doors in Octorber. It was not one of the issues that killed FIFRA. So it would be appropriate for you to include ground water amendments in any core bill that you introduce this year. Putting ground water up front, as you are today, is the right approach. It can be a source of strength and a focus for consensus in a FIFRA reform package.

If you do decide to include ground water protection provisions in a general bill, then I would make three very general suggestions.

First, use a broad definition of the ground water resource that is to be protected. Some will say to you that we need only protect ground water that is likely to reach a drinking water well. I disagree with that for what I think are three very good reasons. One, as we have already heard from witnesses, this one in particular, ground water is a very complex and poorly understood resource. What is or is not likely to make it to a drinking water well is difficult to determine in advance. Two, our need for water supply is constantly increasing and changing location. What we contaminate today may be the source of a community's drinking water tomorrow. And even if it is not needed until the next generation, it may remain contaminated by today's activities.

In my own head I compare the two kinds of drinking water problems that we have; the ground water versus the point source pollution problems that we have, and I think about every time it rains, Virginia ends up in the Potomac, and that is the kind of thing we are used to dealing with; but the reality is that the drinking water that we draw in this area probably was rainfall about the time that the Founding Fathers were signing the Constitution, and that is a very, very significant difference in the resource.

The third point, I think, is that we use our water for purposes other than drinking water supplies, including live stock watering, irrigation, and industrial purposes. Water that humans wouldn't drink has value for these other purposes and ought not be consigned to the role of a waste dump or a sink for pollution.

My second general suggestion is to take a prevention approach to the problem. Do not depend on detection and correction of contamination as a ground water protection strategy. There are some who say that we can take a point-of-use philosophy with respect to our ground water resources. We could, in this view, use pesticides as needed to maximize crop production and, if some show up in drinking water wells, simply treat the water from those wells to make it safe for consumption. That, I would suggest to you, is a very expensive philosophy.

Recently the State of California conducted a survey of ground water contamination. The analytical technology that they used to test for the full range of pesticide contaminants cost approximately $2,000 per sample. How many farm families can afford a water well test every few months to see if their supply is safe to drink? And that does not even touch the tremendous cost of treatment technology, if contamination is found. A protection philosophy based on point-of-use detection and correction is not a thrifty philosophy and it is not in line with the needs and means of America's farm families.

I am somewhat concerned that the bill the Senate passed last year is not sufficiently preventive. It is more reactive. It responds to contamination after it has occurred and been detected. We can make it more preventive by firming up the triggers and by providing the farmer with more information on the interaction between soil, climate, and chemical at the time the pesticide is applied. Perhaps there are other preventive measures that you can develop right here in your committee process.

Third and last general piece of advice is, if you incorporate the standard like the ground water residue guidance level in a bill, make sure the standard is health-based and is not set according to some risk balancing criteria embedded in the old FIFRA law. When we had our hearing last September, I asked each of the witnesses representing EPA, the chemical companies, the farm community, and the environmental interests whether a ground water protection bill should be based strictly on health, without any balancing for economic benefits, and they all agreed that human health was the only sound foundation for a standard.

So those are my three general points, Mr. Chairman. A broad definition of the resource. A prevention philosophy. And a health-based standard.

Let me conclude by offering you the full cooperation of those of us on the Environment Committee. You know we have an interest in this question. We plan to introduce a bill called the Ground

Water Safety Act in the next few days, which is modeled on the amendment from last year, that your committee wrote, but includes a few improvements. We would be very pleased, if you would join us on this bill. We have circulated the bill in draft form to a broad audience and have received a number of comments in writing which I have with me. I look forward to working with you, Mr. Chairman, and the members of this committee on these questions in the coming weeks and I thank you again for allowing me to participate this morning.

We are in the middle of a trade markup right now. I really appreciate this.

The CHAIRMAN. Dave, I really appreciate your taking the time to come over. This is extremely important. This is a case where the Committee on Environment and this committee will have to work together. Every Senator will really have to be concerned about this, because so much of this affects rural areas, and every one of us has a rural constituency to a greater or lesser degree.

I think it is very important. I just want to underscore the last of your three points, whether human health was the standard that should be followed, rather than a balanced economic one. I agree strongly that has to be the basic standard.

I suspect that some of the chemical companies' lawyers who study trends in liability and insurance companies are probably telling them the same thing: if they were to debate an issue before a jury at some point, that health matters more than economic balance.

I look forward to working with you. I know you have got to go back to Finance; and again, I appreciate having you here.

Senator DURENBERGER. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Bond, you were next on questions to Dr. Hallberg.

Dr. Hallberg, to really make this an Iowa show, I am going to turn it over to Senator Harkin.

Senator HARKIN [presiding]. You have just got to get used to that New England accent.

Maybe I should change the spelling of my name; that would be easier.

The CHAIRMAN. Senator Harkin told me the other day he was listening on a squawk box, and he kept hearing this—being referred to by me. He thought it was very nice, very complimentary; he just did not recognize the last name.

Senator HARKIN. Thank you, Mr. Chairman.

Dr. Hallberg, we are pleased to hear that your scientific study confirmed what we have seen in Iowa; farm families are themselves highly interested in the issues of human health, because they are the ones who are drinking water from wells in these areas of pesticides. That is why I think we have a very ready and willing constituency to work with on these problems.

I was a little bit concerned when you indicated that you saw continuing increases in pesticide levels in ground water. Are the control strategies that have been adopted, the limitations on applicators and others not having any impact? Have we gone through all this rigamarole on the limitation, regulation, and instruction of pesticides and chemicals and not made an impact?

Dr. HALLBERG. I do not know that we have not made an impact; but I think we have not been looking at it very long and we are still trying to sort out what the situation is. And there is, because of the time relationships with ground water, there is a time lag between what we do and then what we begin to see in the ground water.

The most responsive systems—and let me use nitrogen as an example, because we understand this better—in the most responsive ground water systems, we have seen almost a concurrent increase from the 1950's on to the 1980's of nitrates increasing in ground water as we increase the land application of nitrogen and more or less our nutrient management.

But in deeper ground water sources, in the western part of Iowa for instance, we have got some municipal water supplies that are considerably deep, in relative terms, at least they are deeper water supplies. In shallow ground water, supplies in the same area showed this linear trend, basically within a few years of when we really began to accelerate the use of nitrogen fertilizer.

These deeper water supplies that the towns are using are just now in the past 3 to 4 years, beginning to show the increases in chemicals that may have started 20 years ago, in these shallower water supplies.

This is part of the problem that we are still trying to sort out. We have a very limited data base on pesticides; but what we do have suggests that we are seeing increasing persistence and occurrence of pesticide residues in our water supply. Partly that is inevitable. Indeed, if they escape from where they are supposed to be, if you will, and get in the water just because of the time involved and the expanding use of such products.

We are at kind of a plateau, now, in the 1980's, in terms of chemical and fertilizer use, with the system bouncing up and down. It has just stabilized in the last few years. If we hold conditions the same as they are right now, I think residues will still be going up for awhile. But there are certain things that we can do in terms of management even with what we already know with that data.

Senator HARKIN. Dr. Moore had indicated that perhaps there were areas in which the level of contamination was going down. Have you seen any of those in Iowa, and can you give us some idea, with specific regard to your State, how long some of the shallower ground water sources would take to either flush out or eliminate the contaminants that are present?

As Senator Durenberger suggested, the ground water we are drinking fell as rain at the time of the founding of this Nation. Is that the kind of timeframe we are talking about for a ground water system to clean itself out?

Dr. HALLBERG. Well, you certainly can. You can talk even longer than that, regarding the deeper ground water supplies. In the shallow parts of the system that are now most impacted, if we ceased all the activities that produce contaminants—not just agricultural, but otherwise—even in those, it would be a decade, probably, before we would see a change in the condition, I think.

We have done a study in the Big Spring Basin Demonstration Project, and that is a very responsive ground water system. We think—we would hope that working with farmers there, within 2 to

3 years we will actually be able to demonstrate changes in concentrations, in a 2 to 3 year timeframe; using better management. But that is an unusual situation.

In some aquifers we are just now seeing the effects of 20 years ago.

Senator **HARKIN**. As a layman looking at scientific challenges, nothing seems to be more perplexing than the problem of trying to clean up a ground water source. Have you found any promising approaches to cleaning up ground water? Have you found that some of the pesticides can be neutralized or degraded with injection of various other agents, perhaps counteracting agents? Have you found anything at all that looks promising?

Dr. **HALLBERG**. Well, there are certain things that interact with contaminants, but they are only economic, really, on a very small scale. If you have a severe point source problem that you have to contain. On ground water, we are trying to come to grips with things for the first time that we dealt with in only surface waters before, and there are point source versus nonpoint source considerations.

When we talk about the nonpoint source aspects of this, it becomes so pervasive we do not have economical means to do that. We are talking about 90 percent of the land area of Iowa and a similar area, probably, in Missouri devoted to agriculture; and there is no economic way to go and treat the ground water in that type of regional area.

Senator **HARKIN**. Thank you, Doctor.

Senator **BOND**. Dr. Hallberg, would you bring Senator Leahy and the committee up to what Iowa is doing right now in terms of their legislation on ground water? What is the latest chapter in that?

Dr. **HALLBERG**. I did not read this morning's headlines, so I do not know the latest chapter, but we have some very heated debate going on in Iowa over what is called the ground water bill, or sometimes the ground water protection act.

It is based on, at least in part, a ground water protection strategy that was developed by our Department of Natural Resources.

In essence, this can be characterized as a plan of action on the various kinds of ground water, sources of ground water contamination; from underground storage tanks to land fills and of course in the agricultural sector. And it was in that process that we identified agriculture as the number one problem area.

The bills that have been put forth in the Iowa Legislature at least on the House side, set the tone policywise, to protect ground water, to the extent practical. It would say if it is practical, we want to eliminate the sources of contamination in ground water.

That does not mean it is a zero discharge law. Again, we have the possibility of aggressively trying to minimize, especially the contamination of the water supplies by chemicals. In terms of safety and the general public, we found that they do not feel comfortable even with standards when they know the nature of some of these chemicals.

Also, the bills at this point in the legislature proposes to raise a variety of revenues, taxing every and all sources of contamination. That was meant somewhat facetiously, but there were increases on fees to landfills, for garbage disposal, with a mandate that was passed last year that we had to phase out landfilling, had to develop alternatives.

More to the focus here is that in the agricultural sector they propose a variety of fees, on agricultural chemicals, on pesticides and on fertilizer to raise the money to go into what we call our Agricultural Initiative.

Now that has taken some bad licks. It has been called a variety of things by a variety of people; but the farm community has endorsed it. The bottom line is what we set out to do is a very aggressive program of interrelated research, demonstration works on the farm, and public farmer education.

Trying to balance the goals—I think the thrust of it, we started it this year; in a program called the Integrated Farm Management Demonstration Program.

Senator **Harkin**. One of the reasons I was raising this issue is to get beyond that. As you point out, a lot of these ground water sources do not really adhere to State boundaries; they cross State boundaries. So when just one State takes some action, that might not solve the whole problem.

The question I want to ask you, Dr. Hallberg, is, do you see the need for a greater Federal role in this whole area, or are you in favor of just leaving it to the States?

Dr. **Hallberg**. Yes, there are so many local things involved with ground water, and the States have to get active on it. There is certainly a need for a greater, stronger Federal presence; I think for matters of consistency, as you point out, this perhaps becomes particularly true in some of the areas we are discussing here, with agricultural-related programs.

Consistency not only in terms of the statute, but enforcement that may be necessary. We feel can do a heck of a lot with voluntary programs in the farm sector in Iowa.

Senator **Harkin**. Do we need more authority for the EPA?

Dr. **Hallberg**. I am not sure we need more authority, frankly; I think what we need, especially in the ag sector, I guess what I call a good dose of IPM. Though we are talking about pesticides, I don't really mean Integrated Pest Management, but rather I would like to see some good integrated and innovative policy models.

We would not like to see more of the same, if you will, and I think that innovative approach is something that is currently lacking. With the separation of ground water from drinking water, for instance, the emphasis on a drinking water program is still an overtone of programs.

We need to look at better balancing of how we might phase out those older pesticides, which are much of the problem, and encourage the development, where they are needed, of new technologies. I think we need to evaluate and direct the system a little better.

Senator **Harkin**. Do we have a lack of Federal standards or State standards regarding contamination of ground water?

Dr. **Hallberg**. We have few standards on most current chemicals. Dr. Moore said earlier there are a number of health advisory type things in the development; it is part of the nationwide ground water protection strategy. But some States have gone to setting their own standards, and some States are doing, in my opinion, a better job of setting standards than EPA has been able to do.

But there are challenges even within States that have gone to setting their own standards.

Senator **Harkin**. Well, those are the questions that I wanted to go over. Whether or not we expand the Federal role and the EPA's role in this, how much authority they need, and whether or not we are spending enough money in this area. These things all cost money when you get down to the bottom line. It costs money to do the testing, and it is going to cost some money to get farmers to shift practices et cetera.

As one farmer said, "You know, I feel like a dope addict. I'm on pesticides, I'm on herbicides, I'm on nitrogen fertilizer," he said, "but I can't get off them, even if I want to, because I'll lose all this money." In addition, the way the Federal farm programs are set up, if the farmer sets aside some of his land, he is paid on production. So the more he produces the more he makes.

Therefore, if fertilizer and herbicides are cheap, why not use them to produce more? Even though farmers are caught in a situation where they might like to reduce chemical use, obviously, econimically, they cannot reduce their applications of herbicides, pesticides, and fertilizer. There needs to be some kind of transitional effort there.

It all costs money, and I thought I would ask for your thoughts on the funding levels for these various efforts that address the ground water problem.

Dr. **Hallberg**. That is obviously a needed concern. That is what in part came from the debate in Iowa, was the revenue, some of the revenue-raising aspects of it. And it was not so much from the farm sector as it was from other sectors. Someone suggested they had taxes proposed on everything from household chemicals to garbage—someone suggested that most factions should be satisfied as we treated all sources of pollutants equally, but at the same time this managed to offend everyone.

We have a need for research. We need some independent work, both on the health front as well as the environmental front.

One of the things we have to support in the transition is educational programs. Farmers have been responsive in this issue, but they cannot just jump in to make major changes. Our State program would propose the spending of anywhere from $2 million, depending on what happens, to $6 or $7 million a year; which is the biggest chunk of money we have ever put into this type of thing, you know, strictly for educational and demonstration programs; and the State working with the farmers to help ease the transition.

Senator **Harkin**. Well, Dr. Hallberg, thank you very much for your excellent testimony and all the work you have done in Iowa.

On our next panel, we have Dr. Stuart Cohen and Diane Cognal from Bakersfield, California.

Dr. Cohen was a scientist with EPA for 11 years. He served as a team leader on ground water and the agency's witness in labor proceedings to ban DBCT.

Diane Cognal is from Bakersfield, CA. I understand her children were exposed to drinking water contaminated by DBCP for a period of 6 years.

We welcome you to the committee. Dr. Cohen, go ahead and proceed, and then Diane, we will call on you to tell us about your experience.

STATEMENT OF DR. STUART Z. COHEN, MANAGER, GROUND WATER PROGRAMS, BIOSPHERICS, INC., ROCKVILLE, MD

Dr. COHEN. I have been asked to give a brief summary of DBCP, what it is, why it contaminates ground water, its regulatory history, a sort of background for the subsequent statement by Mrs. Cognal. Also to make a couple of general statements about the issue of pesticides in ground water, which Dr. Hallberg covered pretty well.

First I would like to comment on the statistic that Dr. Hallberg made earlier, about the latest tally of at least 22 pesticides found in 24 different States. When I first started making that tally, I never had the preposition "at least" in front of it, because I felt pretty confident we did not have pesticide investigations in other States. So many States are doing so many programs that it is very difficult to keep track. So as Dr. Hallberg said, yes, the number is probably much higher.

DBCP was a liquid soil fumigant used over about three decades, from the mid-1950's to about 1979 in the Continental United States and a few years after that in Hawaii. It is very effective against nematodes. They are microscopic worms which destroy root systems of plants. That is a very bad problem for farmers in certain areas. It can wipe out peach tree orchards, it can wipe out pineapple fields. DBCP was the prime pesticide for that use.

Its prime use sites were in the Far West and the Southeast, California, Arizona, Georgia, Florida, and Hawaii.

It has been shown to be a carcinogen, in several laboratory studies, in rats and mice. If you use the standard de minimus risk figure, which I think is a factor these days of 1 in 1 million that yields a very low upper estimate of 25 parts per trillion, 0.025 parts per billion in drinking water for a lifetime exposure and a lifetime risk.

Various epidemiology studies have been performed in California and they suggest, but do not prove, a positive association between DBCP in drinking water and leukemia and gastric cancer. It has been shown to have testicular toxicity in humans, causing sterility in workers that handle it, and genetic toxicity in laboratory animals.

In 1979, EPA became aware of additional exposure data. These toxicity data were generated from 1977 to 1982. What changed the picture was in 1979 exposure data came in showing dietary residues in citrus, peaches, and grapes. Of workers, as I mentioned, actual human effects on them, and ground water. We were finding it in ground water in California, Arizona, Hawaii, Maryland, and South Carolina.

According to a 1984 summary by the State Board of Water Resources in California, over 2,000 wells, approximately 2,500 wells, contained detectable levels of DBCP; and at that time probably half of those wells exceeded the action level.

REGULATORY HISTORY

In 1977, EPA and California issued partial or complete suspensions of the use of the chemical; 1979 was sort of our baptism by fire for pesticides in ground water—it sort of kicked off the whole field. Several of us were on the witness stand, and the judge's decision was issued in the fall. The Administrator followed that, and all continental uses of DBCP were banned at that time, a hazard was declared; and then about 5 or 6 years later, the remaining use in Hawaii was banned.

I have several statements about the issue of pesticides in ground water. The potential number of people that can be exposed is high, although the concentrations are variable and often low; the significance of the concentrations are definitely variable.

It all hinges on a topic discussed here earlier, and that is the health effects of these kinds of chemicals. I estimate that the number of wells containing detectable levels of pesticides are usually in the several millions; the number of people is in the millions; the number of wells are probably 100,000 or greater.

The national survey that Dr. Moore discussed earlier this morning is going to be a good statistical study which will address those issues.

Herbicides and nematicides, because of their mode of action, occur more frequently than pesticides in ground water.

Pesticides occur most frequently in ground water because pesticides are mobile, they are not bound by soil, they are transported in water, and they are persistent and not very easily degraded. Many pesticides depend on their mobility and persistence to be efficacious against target pests. Those pesticides which are mobile and persistent and toxic are the ones that caused us the most regulatory concern when I was at EPA.

The greatest unknown is the health effects of these compounds. Do we have a national problem? To answer that question, which is on everybody's mind, depends on what the health guidance levels will be on several of these chemicals, especially the large volume herbicides.

The other great unknown is predicting concentrations in ground water. As Dr. Moore said, we have got a pretty good idea of predicting whether a pesticide is going to leach into ground water, but not a good idea of how to predict the exact concentrations, and then even further, matching this up against actual health guidance levels.

With regard to human effects, it is very difficult to establish cause-effect relationships in this area because of the compounding factors. The California study, as I mentioned earlier, compounding factors were dietary; that farmworkers have diets which are different from others in the rest of the United States, with exposures throughout a lifetime.

So for the present time, EPA relies on laboratory data to make toxicity judgments.

That is all I have. That is the direct part of my statement. I am willing to answer any questions.

[The outline of the oral testimony of Dr. Stuart Z. Cohen, Ph.D. follows:]

OUTLINE OF TESTIMONY
ON DBCP FOR SENATE AGRICULTURE COMMITTEE - APRIL 29, 1987

I. USES OF DBCP (1,2 - dibromochloropropane)

Liquid soil fumigant used from mid-1950's to 1979 (to 1984 in Hawaii).

Very effective against nematodes - tiny worms which destroy root systems - for use on peaches, citrus, pineapples, soybeans, grapes, turf, plums, nuts, peas, beans, cotton, etc.

Prime use sites in California, Arizona, Hawaii, and Southeast.

II. TOXICITY

Carcinogenicity - 0.025 parts per billion (25 parts per trillion) in drinking water yields upper estimate of 1 x 10^{-6} lifetime risk for lifetime exposure.

Various epidemiology studies performed in California suggest, but do not prove, a positive association between DBCP in drinking water and leukemia and gastric cancer.

Testicular Toxicity - demonstrated in humans

Genetic Toxicity - potential for humans

III. EXPOSURE

Food

Workers

Ground Water - Findings in California, Arizona, Hawaii, Maryland South Carolina

As of April 1984, 2522 wells in California contained DBCP with estimated exposure to over 700,000 people.

IV. REGULATORY HISTORY

1977 EPA & California partial or complete suspensions

1979 EPA Suspension order and trial/hearing. Suspension of all registrations in continental U.S.

1985 EPA cancellation of remaining pineapple use

V. POTENTIAL NATIONWIDE EXPOSURE TO PESTICIDES IN GROUND WATER

Potential number of people high.

Significance of concentrations variable - dependent on EPA health guidance levels.

Herbicides and nematicides occur more frequently than other types of pesticides in ground water.

Stuart Z. Cohen, Ph.D
Manager
Ground-Water Programs
Biospherics Incorporated
Rockville, Maryland

Senator **Harkin**. Let us go now to Mrs. Cognal. I see you do not have a prepared statement, so please tell us your experience.

STATEMENT OF DIANE COGNAL, BAKERSFIELD, CA

Mrs. **Cognal**. I live in Kern County, which is in the San Jaoquin Valley, one of the richest farm belts. We have two children who attended the Norris School in the Norris School district. The school is the district, and it is surrounded by cotton fields.

In 1979, the school was notified they had high nitrates and DBCP in their well. The health department notified the school that consumers avoid internal consumption of the water and that bottled water be utilized. DBCP is a cancer-causing agent. They sent over 12 letters to the school, 5 of them required notices in writing. For nearly 5 years the children continued to drink DBCP-contaminated water.

There was testing by the State on the well. They were automatically sent a letter from the health department with the results. The superintendent of that school was also the principal; only acknowledged one letter, the first one. He did not know what DBCP was. Norris School sent a veterinarian out to check the water. The letter was signed by the health department, two environmental specialists.

Norris School never called the health department to find out—because if you can't see it, you can't smell it, and you can't taste it, it's not bad. Norris School Superintendent Waite did not know what it was. C. Erwin Waite also knew that it was an action level which is not legally enforceable. It was not a standard which is enforceable. So Norris School went and had their own testing done——

Senator **Harkin**. You mean the school had testing done?

Mrs. **Cognal**. Yes. Norris School had their own testing done. The test results did not show DBCP. The reason being at that time the lab that they had doing the testing was not State certified to do DBCP testing. Norris School felt the schoolchildren, kindergarten through eighth grade did not warrant supplying bottled water.

So as the children, throughout the years were drinking DBCP, they could have been on bottled water. We had the California State Drinking Water Act. That enabled public drinking water wells to get taxpayers' money, a grant for a new well. Now, you sign a document yea-thick stating that the prerequisite—you have contaminated DBCP water and you need safe drinking water.

Norris School also checked, because we were building a new junior high, on how much it would cost if he hooked up to an existing water company. That would cost Norris School District $80,000 to $90,000. C. Erwin Waite could get taxpayers' money, our tax money, not out of the school's pocket under the California Safe Drinking Water Act, to drill a new well, which he proceeded to do. Never in almost 5 years were the parents or students told that the children were drinking poisoned water. We use the words herbicide, insecticide, pesticide, homicide. We must remember what they mean—death. DBCP is a poison in our drinking water.

Then when it came out in the newspaper that these children were drinking DBCP-contaminated water—we were never to know, because the school actually went to the health department and asked them, "Could you hold off? The new well will be in in a couple weeks."

Then in 1980, my son we noticed, was not growing. We had him tested. He had suppressed testosterone, male growth hormones; and then I find out that he has been on contaminated DBCP water. I feel there is a connection between his non-growth and drinking pesticide-contaminated water. DBCP caused male sterility in the Lathrop employees that made DBCP.

All the testing at this time is on laboratory animals; epidemiologists do not have humans to study. Epidemiologists say it affects your weakest genetic link. At this point in time it is not life threatening; he is growing now, but what I see as a parent, when it takes 2 years for a tooth to come in. That's what I can see. What happens inside of his body that I cannot see? There were 500 children at the school at this time, in kindergarten through eighth grade. When you toast your children on their birthday you raise your glass and say, "Here's to your health and happiness." That is now in jeopardy.

This is how I learned about DBCP. And further, I went to the Department of Food and Agriculture in Sacramento, because I wanted an explanation, because in the State of California you have to have health effects tests to register chemicals. I wanted to know the results of those tests. Food and Agriculture did not keep records until 1979 or 1980, of people that requested the health results of the testing. It was a trade secret.

What the Department of Food and Agriculture did was to send out their standard 10-day letter, and that went to the chemical company—the reason being they did not want to be involved in any kind of lawsuit. They were just protecting themselves, not looking out for the health and safety of the human beings.

What will happen to future generations when the drinking water gets worse? We cannot live without water. We must act now to protect our drinking water. Future generations will have a higher death rate due to drinking contaminated water. Human beings have rights, not chemicals.

You can't see, taste, or smell the poison in the water.

Senator HARKIN. What area of California are you in?

Mrs. COGNAL. My area—Kern County allowed use of a converted agricultural well. That is no longer allowed. We have got stricter well regulations, but we have what we call hot areas on the maps where we have heavy DBCP and EDB. DBCP comes with nitrates, for some reason. They are together.

We have also got a voluntary amendment to, like our board of supervisors; sort of like your termite inspection. To where people—because out in this area we do not have a water company that can come in. If you want to live out in this area, you can either drill your own well or a contractor will come in and drill a well. Before, the wells were never water-qualified tested. Now the well must pass water purification tests before you can build. But there is a problem with many existing wells. They are low-level; they are perforated above and below the Corcoran clay. Contaminated water is mixing with the good water and contamination is spreading.

We have homes out there that you cannot get water without nitrates and DBCP. You can use osmosis for the nitrates, and you can get a charcoal filter for the DBCP. You have to know when to remove that charcoal filter and place another one. What are you going to do with the charcoal filter? That's solid toxic waste; that is DBCP. You are going to wrap it in plastic and you are going to send it to the dump. To be legal it should be sent to a class I dump. Our dump is above our ground water table. That solves the problem? It spreads the problem.

The company that sells the filter should give you two filters; when you use one up, you have a package, you send it back to them, and they take it and dispose of it properly.

Senator Humphrey. In your area, is the level of concern still quite high?

Mrs. Cooper. Very high. Very high, because we are finding more wells, and we are doing testing and we are finding out this last year we had record snows—because we only get 7 inches of rain a year; that's it. We must rely on our ground water. And they recharge this area. The nitrates went down, but the DBCP stayed the same. EDB and 1,2-D are also present. How many more chemicals are in our drinking water we haven't tested for.

There are no guarantees on this, and the sad part is they are still building homes, and it is the homeowner who is going to have the final burden. Bottled water and filters solve one problem—we bathe our children and families in DBCP water. It goes through the skin and is inhaled into the bodies.

Senator Humphrey. Dr. Cohen, how would you characterize the extent of the pesticide ground water contamination, nationwide today? Is it something that we have got to be concerned about some time down the road or now? If now, what level of concern should we have right now?

Dr. Cohen. Well, there is definitely concern now to have more data to find out what is the extent of the problem. It is definitely a regional basis, certain areas.

In the San Joaquin Valley of California where Mrs. Cooper lives, the southern part, and throughout the southern parts, it is problematic for DBCP and other pesticides.

Florida has a problem in the central area.

You are familiar with the work of the Iowa State government there. The hydrogeology is similar in those areas I have just described to you, and therefore monitoring data.

The question then is, where is the marriage between hydrogeology and places where pesticides can result in a public health problem, and that is not known yet, and I do not know what the answer to that question is going to be.

Senator Humphrey. I repeat my question. How do you characterize the level of pesticide contamination today?

Dr. Cohen. Well, I can just give you numbers, documented numbers and not say if we had a sample of every well in the United States, what those numbers might be.

There have been about 10,000 wells—a rough estimate—10,000 wells nationwide that were sampled for pesticides in ground water. As a result of normal use—I am not talking about the point source problems that George had mentioned earlier, or industrial waste sites or Superfund.

Of those 45,000 wells, 11,000 showed detectable levels of pesticides, some of which are DBCP. Now half of those 11,000—have pesticides exceeding some sort of guidance level.

Now in somebody's testimony and I can't remember whose it came up in, what came up is that all these studies just looked for one pesticide; so a lot of the negative wells may have had other pesticides, but these studies did not have the resources to look for those.

With regard to the relatively high proportion of pesticides exceeding health guidance levels, after a little bit of thought I think that can best be explained by the fact that people are most likely to monitor the chemical that is most hazardous.

There are 13 million wells nationwide; and what I talked to you about is a biased sample of just 45,000 wells, so less than a half percent of all wells in the sample nationwide.

In the final analysis, I just don't know.

As I said, some rough figures at the end of my presentation. I think it is reasonable to expect that several millions of people are exposed to pesticides in their drinking water, but it is of unknown toxicological significance.

Once EPA publishes some health guidance levels, which is extremely important, then we will know the toxicological significance of this finding.

Senator HARKIN. You are not just talking about several million Americans who happen to have a well in their back yard.

Dr. COHEN. Right, I am talking about public wells also.

Senator HARKIN. You are also talking about municipal wells?

Dr. COHEN. Right. There are about 53,000 municipal well systems that have an average of, I do not know, a couple wells per system; there have been various estimates from one and a half to three. And I think rural America, we have seen statistics that 97 percent of rural Americans are served by wells.

Senator HARKIN. In the last couple of years, I had someone ask about the number of wells with nitrates in them. He said, fortunately we do not get our water from a well, we get it from our municipal water supply. Well, the municipal water system got it from a well, but he just did not make that connection; to him "well" means you have a well in your back yard.

People may be confused on this point.

Dr. COHEN. One problem generally—municipal wells are going to be less of a problem than private wells because they are deeper, they are better constructed.

You were asking Dr. Hallberg about temporal trends, what happens once you stop using pesticides. Well, in California where they stopped using pesticides, DBCP in 1977, there were some municipal wells in Fresno County that, as of about a year and a half ago, the concentrations of DBCP continued to increase.

We see a similar phenomenon in deeper systems. We have seen this similar phenomenon in the outer part of Long Island, that the shallow wells respond much more quickly to a regulatory action; so that if you can imagine a trend analysis that the outer part will be decreasing, in the shallow wells over a period of years, and in the deeper wells it will be increasing. Eventually, of course, the concentrations will decrease.

Napa River Valley was a situation where EDB showed up 16 years after it was last used; admittedly, at very low levels.

So the trend analysis, in deeper wells you usually have a higher level of protection, but it does not mean total protection. And that over time these wells can also start showing some detectable levels.

Senator HARKIN. Did you have any dealings with the Federal Government, or was this State and local government dealings only?

Mrs. COGNAL. State and local.

Senator HARKIN. How would you characterize the responsiveness of the State and local people?

Mrs. COGNAL. When the health department knows the area is heavy EDB and heavy DBCP, they should not allow building in those areas. The homeowner is then liable.

For instance, you have a community of homes; the well is starting to show traces. What do you do about it? Can you afford to put in a new well? Drilling a new well costs $30,000 right now. Do you own enough land for a new well?

FHA/VA now requires water quality testing in certain areas.

There are new houses out where I live, in certain areas—if you buy a second-time home, a used home that is not monitored by the State, that is not monitored by the county, you do not know to check the water. How many people go into buying a new home know to check the water? They turn it on and see if there is any rust. It is a poison.

It's the man in the John Deere hat and plaid shirt who gets the blame for the contamination. He is the one the public sees using the chemicals. He uses DBCP as an asset to his business and then finds out years down the road that DBCP is cancer causing, birth defects, mutant, and a liability to his business and his family's health. The American farmer is not to blame. The chemical companies are.

Give the farmer some options. He is now chemically dependent. He cannot just say "No." He cannot leave the farm. He needs funding to try to get off the chemical treadmill.

Senator HARKIN. The problem is that there are just a lot of places that you point to. There are 45,000 wells that you tested, and of those, 10,000 had problems, right, Dr. Cohen?

Dr. COHEN. Right.

Senator HARKIN. Then there are hot spots, correct?

Dr. COHEN. I think a lot of those hot spots have been identified; but as I said, I think there are other areas where there is horrible hydrogeology and there has not been excessive testing done. That has been largely a function of the awareness of State officials and their competence.

Senator HARKIN. Well, I think we have ignored it too long and hoped that it would go away. However, it is not going to go away, and neither are the herbicides and pesticides and fertilizer. As Dr. Hallberg said, we have to have better management systems, and we have to be aware of the long-term effects of these.

Certainly, a lot of the issue is still open to question. I know there are, in many cases, no hard and fast data, but, to me, the burden of proof has got to be on someone to tell me that making 2,4,5-T or something like it, is, or is not going to get into the water and hurt me.

Thank you both very much.

The committee will stand adjourned subject to the call of the Chair.

[Whereupon, at 11:12 a.m., the committee recessed, to reconvene at 10:50 a.m., in room SD-562, Dirksen Senate Office Building, Wednesday, May 20, 1987.]

[Material submitted for inclusion in the record follows:]

Attn: Senator Patrick Leahy

MEMO

10889 WILSHIRE BOULEVARD
SUITE 1500
LOS ANGELES, CALIFORNIA 90024

OCCIDENTAL PETROLEUM CORPORATION

To D. A. Guthrie

From J. Wilkenfeld

Subject: Re-entry to DBCP Market

Date December 11, 1978

cc: Bruce McWilliams
Jim Plummer

As you requested, I have reviewed the memo's by D. M. Smith dated 11/9/78 and M. G. Rice dated 10/26/78 and the report, Business Opportunities for AG Products West. In discussing this proposal with Mel Rice, he indicated that until the State of California permits the use of DBCP on agricultural crops, he does not propose to proceed with this matter. It is my understanding that the State of California has rejected requests for permission to use the material and, in addition, the government of Mexico has shut down the two manufacturing plants for DBCP that were operating in that country.

Should there still be a desire to continue consideration of manufactured DBCP, there is a need for inclusion of an estimate of potential liability in the economic evaluation of the project. This becomes especially important in a case such as DBCP where known health effects have been observed, and the product has received such extensive adverse publicity.

As we discussed earilier, a method for evaluating the future potential liability is needed. Until we have a formalized procedure this will have to be done on an adhoc basis. The following are my thoughts on how this might be done. This should not be taken as definitive. I have reviewed the approach briefly with Jim Plummer and Bruce McWilliams. They both feel this might be used as a starting point in such considerations.

1. Estimate the maximum number of people in-house who would be exposed to DBCP during the course of manufacture. This should be exposure to any amount, independent of whether it exceeds the permissible levels or not.

2. Estimate the maximum number of people who might be exposed to DBCP in transportation, distribution and use. In determining the number of people exposed during use, assume exposure might occur during 150% of the normal half-life of DBCP.

3. Determine the normal temporary or permanent sterility rate in the general population. Also the normal cancer rate in the general population for the type of tumor DBCP is suspected of causing.

4. Assume that 50% of the normal rate for those people exposed may file claims of effects from the exposure, determine the number of potential claims for sterility and cancer.

5. Based on the Insurance Department's (or legal department's) estimate of the probable average judgment or settlement which would result from such a claim, calculate the potential liability including 50% for legal fees and other contingencies.

6. To this should be added the expenses for special training programs for handlers and users along with any required staff for monitoring the proper handling of the material during manufacture and use.

Should this product still show an adequate profit meeting corporate investment criteria, the project should be considered further. This of course assumes that we do not feel there is in fact any significant risk due to exposure at the planned levels. Doctors Zavon and Nees should attest to this. I note for example on Page 2 of the October 20 memo that regulated areas will be established whenever the permissable exposure limit is exceeded. It is my feeling that any area in which there is probability of exposure to DBCP at any level, should be regulated and access limited to trained, authorized people only.

JW:m

This is a health and safety issue. There has got to be moral judgement on right and wrong. The bottom can no longer be profitability

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Pesticide Residues in Food

WEDNESDAY, MAY 20, 1987

U.S. Senate,
Committee on Agriculture, Nutrition, and Forestry,
Washington, DC.

The committee met, pursuant to notice, at 10:50 a.m., in room SD-562, Dirksen Senate Office Building, Hon. Patrick J. Leahy (chairman of the committee) presiding.

Present or submitting a statement: Senators Leahy, Pryor, Daschle, Bond, and Wilson.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

The Chairman. The Committee on Agriculture, Nutrition, and Forestry will be in order.

I do want to thank our first panel, the National Academy of Sciences, for being here. I know that they have come directly from an extremely important press conference downtown to be here. And I appreciate that because I know their schedule was tight.

We will be talking about the safety of our food supply today. There is no issue more important to the American public than the safety of its food supply. The food we eat and the food we feed our children must be the safest in the world. In a Nation like ours, there is no reason why it should not be.

In an annual consumer poll taken by the Food Marketing Institute, a trade association representing about 1,300 supermarkets, wholesalers and manufacturers, 75 percent of shoppers surveyed this year said that they are worried about pesticide residues in food.

Our system of regulating food is set up to make sure that the American people do not consume food that contains unsafe levels of pesticides or other contaminants. The National Academy of Sciences report, which was released today, confirms that system has not succeeded. We simply must do a better job than we are doing now. doing now.

The report presented here today by the Board on Agriculture of the National Academy of Sciences dramatically demonstrates the stakes faced by the American public. According to the Academy, 1½ million Americans could get cancer because of only 28 pesticides. One group of pesticides alone, EBDC's, could result in 240,000 extra cancer cases.

The NAS is not alone in raising these concerns. In a recent report, "Unfinished Business," EPA identified pesticide residues in food as one of the Nation's most serious health problems.

There are a large number of older pesticides about which EPA has serious underlying safety questions and has as yet taken no action. In the pesticides used today, 9 out of 10 lack the total scientific testing necessary to determine whether they are completely safe.

I am eager to hear today what the EPA thinks of the results of the report and what the Agency intends to do about the risk to the public from carcinogens in food.

We must have stronger and better regulatory action. Much more research about application rates, time of application during the growing season, and the impact of tightening tolerances is needed to improve the safety of food in the short term, and I believe this is a task the EPA can accomplish. In fact, they are going to have to accomplish this because, as the NAS study indicates, we could eliminate as much as 90 percent of the estimated cancer risk posed by the pesticides studied by dealing effectively and immediately with just 12. Dealing with only 12 will remove 90 percent of the risk.

That certainly is something that we have to think about on this committee. We simply cannot delay administrative and legislative action dealing with these problems. FIFRA reform has to be a top priority for this committee.

A number of years ago, when Senator Lugar and I did a rewrite of FIFRA, I remember how important it was. Since then, we have acquired new knowledge, and what drove us back then, drives us today.

I am encouraged that the House Agriculture Committee introduced its FIFRA reform legislation yesterday. I am planning to introduce a comprehensive FIFRA reform package after the Memorial Day recess.

I look forward to working with Senator Lugar and the other members of this committee, and with all the witnesses here today to see that we are successful. This report points out the need for reform far more dramatically than I would have thought possible. I think all of us as members of the committee are here to offer support in this effort. I would strongly suggest to anybody who has not had a chance to read the report, read it. If you think that there is any reason why we should delay until this fall, or why we should wait until next year to act on this, read the report, and you will change your mind.

I suspect as the American public reads this report, there is going to be an awful lot of pressure brought to bear on both bodies of the Congress to do something about it.

Senator Lugar has been delayed. Does anybody else want to make a statement? Senator Bond.

STATEMENT OF HON. CHRISTOPHER S. "KIT" BOND, A U.S. SENATOR FROM MISSOURI

Senator **Bond**. Thank you, Mr. Chairman, and let me offer our sincere thanks to you for holding this prompt hearing. This is the second very important hearing that you have scheduled on the impact of pesticides, their possible health risks, and other effects.

We recently completed the first ground water hearing. It was very informative. We learned a great deal there.

Here, in this issue, we are going to be addressing something that has implications obviously not only for agricultural commodities, but the processors and, most importantly, consumers. As we consider legislation, it is going to be essential for us to have the best scientific information so that we can act responsibly, effectively, with risks that have been identified.

I think it is important to note that we have benefited from the use of pesticides. They have become a very important part of our agricultural sector. They have increased the availability of commodities; they have kept food costs low; they improved the qualities of commodities and made many commodities available. However, apparently—and I have not had an opportunity, not had the occasion to review this report—we have many issues which have been raised and which are going to have to be addressed.

The monitoring of the impact, the assessment of the health risks is an extremely important part of this process. If we can, as you indicated in your comments, sir, deal promptly with some of the greatest risks and also set up a schedule of dealing with the other risks, then I am sure that this committee will join with you in moving quickly to deal with those risks and to improve the safety and the health of American consumers.

We sincerely appreciate the time and effort that these witnesses and the other witnesses have taken to prepare this report. We look forward to hearing their comments.

The **Chairman**. Thank you very much.

The distinguished Senator from Arkansas, Senator Pryor.

STATEMENT OF HON. DAVID H. PRYOR, A U.S. SENATOR FROM ARKANSAS

Senator **Pryor**. Thank you, Mr. Chairman.

Needless to say from the interest in this hearing this morning, we have long awaited this committee report, and we appreciate our panelists this morning coming forward. Mr. Chairman, we all appreciate you scheduling this hearing in such a prompt and efficient fashion.

Let me just add a personal note, if I might, Mr. Chairman and my colleagues. The Honorable Ray Thornton, who is the president of the University of Arkansas, is the Chairman of the highly acclaimed group making the presentation on behalf of the National Academy of Sciences.

President Thornton of the University of Arkansas has spent I don't know how long in working on this report with his colleagues. We are very indebted to you, Ray, for your time that you have expended and the resources that you have been able to bring together to bring this report out at this time.

Mr. Chairman, Mr. Thornton is not only a former attorney general of our State, he is also a former Congressman from the Fourth Congressional District. He has been a longtime and almost a lifelong friend, and he is a great public servant in our State. His being the Chairman adds unusual significance to this report. We look forward to that, and we appreciate you, President Thornton.

Thank you.

The CHAIRMAN. Thank you very much, Dave.

Dr. Thornton was very good to help us to arrange and rearrange his own press briefing on this so they could come immediately here, and I know that is much appreciated by the committee. I want to yield first, before we start with your testimony, sir, to Senator Wilson, the distinguished Senator from California.

STATEMENT OF HON. PETE WILSON, A U.S. SENATOR FROM CALIFORNIA

Senator WILSON. Thank you, Mr. Chairman.

I will not take long because, like you, I am eager to hear the witnesses.

FIFRA has been before us before. And it is because of its importance and much the way that Senator Bond has expressed it, that we are indebted to you for holding this hearing.

I think that he put it well when he focused on the necessary balance that we have been required to strike. Obviously, we have sought in this Nation to provide foodstuffs in a fashion that made them both plentiful and wholesome. And part of the productivity of our agriculture has been brought about by the use of pesticides, but clearly that factor, as laudable and commendable as it is, and as directly as it bears upon the price of food for the consumer, has to yield to the necessity to protect public health. But it is a very difficult balance to strike, even though we must strike it in favor of public health. We are required to be very, very careful that what we are doing is factually justifiable. And as a result of that, these hearings, I think, have an enormous importance.

The interests here pose a very heavy responsibility and a very difficult set of problems. One of the interesting facts that has emerged with respect to enforcement of existing law is that since the seventies the Environmental Protection Agency has been under the gun to reregister some 600 active ingredients of which barely 1 percent have been reregistered.

And just last week, as the Chairman recalls, we, under his leadership, passed what will be for the first time an agricultural title to an Omnibus Trade Act. Contained in that title were provisions which I had put forth asking for equity for American growers but, more importantly, protection for American consumers by requiring that the Food and Drug Administration present to us the kind of plan and monitoring summary that will provide FDA a data base so that their future sampling and inspection of imported foodstuffs will be more than anecdotal.

So, Mr. Chairman, I thank you, and look forward to hearing from the witnesses.

The CHAIRMAN. Thank you very much.

I also welcome the distinguished Senator from South Dakota, Senator Daschle.

Gentlemen, you have given us "Regulating Pesticides in Food—the Delaney Paradox." Chairman Thornton, I will leave it to you to proceed in any way you see fit, and again you have the thanks of the whole committee for being here.

Go ahead, sir.

[EDITOR'S NOTE.—The publication, "Regulating Pesticides in Food—the Delaney Paradox," is available from the National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20418. A copy is retained in the Committee's file.]

STATEMENT OF RAY THORNTON, PRESIDENT, UNIVERSITY OF ARKANSAS, CHAIRMAN, COMMITTEE ON SCIENTIFIC AND REGULATORY ISSUES UNDERLYING PESTICIDE USE PATTERNS AND AGRICULTURAL INNOVATION, ACCOMPANIED BY DR. DONALD BISSING, FMC CORP., PRINCETON, NJ; DR. ARTHUR UPTON, NEW YORK UNIVERSITY, NEW YORK, NY; RICHARD A MERRILL, DEAN, UNIVERSITY OF VIRGINIA LAW SCHOOL, CHARLOTTESVILLE, VA; PANEL REPRESENTING THE NATIONAL ACADEMY OF SCIENCES

Mr. THORNTON. Thank you, Mr. Chairman.

I deeply appreciate your scheduling this hearing so promptly and I want to say very specially that I appreciate the introduction that my lifelong friend, Senator David Pryor, provided to me.

I am joined at the table this morning by Dr. Don Bissing, Dr. Richard Merrill, and Dr. Art Upton, whose credentials are before the committee. I have elevated Richard Merrill to doctor, though juris doctor does not always carry that appellation. He is dean of the University of Virginia Law School.

The CHAIRMAN. Those of us who have worked long and hard to get our juris doctorates don't mind a bit. Let me tell you right now. [Laughter.]

Mr. THORNTON. Well, that's the only reason I feel at all comfortable in your addressing me by that name. Mister is the more usual salutation.

Mr. Chairman, if I may, I would like to submit for the record the formal statement which has been prepared for the committee in the interest of time and make a very brief summary of that statement, and then open to questions.

Thank you, sir.

Our assignment was to review and to report about the laws and regulations governing pesticide residues in foods. Our report does not address actual exposure to pesticide residues. Nor does it comment on the safety of individual foods. It does not suggest any change in eating habits. Our report is addressed primarily to Government, which is presently faced with a crazy quilt pattern of rules and regulations. We suggest that a more rational process of regulation is possible. We recommend the adoption of consistent standards of negligible risk and an analytical framework to establish priorities and focus attention on risk reduction.

Part of the problem arises out of the difference in regulation applied to fresh and processed foods, and the Delaney Clause's ostensible zero-risk standard applies only to processed foods which concentrate. Our committee was asked whether this dichotomy between raw and processed foods makes sense in light of our present knowledge?

The short answer to this question Mr. Chairman, is no. We can discover no scientific reasons for the law's different treatment of pesticide residues on raw as opposed to processed foods. Strict adherence to the Delaney Clause, with its distinction between fresh and processed foods, would eliminate only about half of the potential oncogenic risk posed by the 28 pesticides our committee studied intensively. In contrast, a uniform, negligible risk standard—which we recommend—representing no more than one additional case of cancer for every 1 million people exposed, could eliminate almost all of the potential dietary oncogenic risks posed by these residues.

Mr. Chairman, neither did we find any reason to regulate new pesticides differently from old ones. According to our analysis, about 90 percent of the total potential oncogenic risk posed by the 28 pesticides can be traced to pesticides registered before 1978, when EPA began requiring more rigorous tests. While the Agency has strictly applied the Delaney Clause to pesticides registered after 1978, it has yet to apply it to those approved earlier.

I should caution the committee that our analysis and report assumes that pesticide residues are present in foods at their legal maximum levels. We do not believe this is true for the great majority of foods, but data on actual residue levels present in foods as eaten are limited. Moreover, we were asked to look at levels of pesticide residues allowed under current Federal laws and regulations. The key word here is allowed. We were not asked to determine actual oncogenic risks posed by pesticide residues, but rather to throw up a spectrum on the basis of allowable tolerances to determine whether the present structure of regulation was satisfactorily meeting the public's interest in providing a safe food supply.

Given our finding that potential oncogenic risks are concentrated in a relatively small number of areas, we recommend that EPA identify and focus its regulatory effort on the most worrisome pesticides used on the most frequently eaten crops. The identification of crop-pesticide combinations posing the greatest potential oncogenic risks under current regulatory rules is useful as a priority-setting tool. By using this tool, regulators can direct their efforts toward regulation of fresh and processed foods and of new and old pesticides on a more equal footing.

We also make a point in our report to note the special case of fungicides. While fungicides are critical for the economic production of many fruits and vegetables, almost all of these compounds are known to be oncogenic in laboratory animals, and few effective alternative compounds are under development. For that reason, we recommend that EPA review these compounds simultaneously for each registered crop use, and that it grant or retain tolerances for the combination of fungicides on a given crop that poses the lowest relative risk overall. The effect of this recommendation would be for EPA to examine fungicides as a class on a crop-by-crop basis, rather than approving or rejecting individual fungicides one at a time, as is the case now.

You may ask, "Why not apply the ostensible zero-risk standard of the Delaney Clause to raw and processed foods?" The answer is that such a policy would require that a large number of cost-effective and useful pesticides be withdrawn from the market even though many of these compounds pose very low and possibly no actual human cancer risk.

Pesticides are essential to our agricultural productivity, controlling insect pests, weeds, and crop diseases. Nonchemical pest control strategies, such as biological control of pest species, may someday reduce the need for pesticides, but they are not yet available for many major crops. In the meantime, we cannot and should not jeopardize our goal of providing an adequate and economic food supply for the American public.

To recap then, Mr. Chairman, our committee examined the scientific basis for regulation of pesticide residues in foods. We found that the current law, which judges residues on raw foods by a less stringent standard than processed foods, is difficult to implement and does not provide the best protection of public health. In contrast, a uniform, negligible risk standard, applied across-the-board to old and new pesticides alike on both fresh and processed foods would virtually eliminate potential dietary oncogenic risks from pesticides. At the same time, such a standard diligently applied by EPA need not cause undue hardships for agriculture. By updating the Delaney Clause with such a uniform, negligible-risk standard, the EPA would be replacing the current crazy quilt of regulations with a pattern that is consistent, sensible, and scientific.

We appreciate the opportunity of bringing this report to your attention, and I would be pleased to respond to questions or, more likely, refer them to members of our panel who are seated here.

[The prepared statement of Mr. Thornton follows:]

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[illegible]

significant increase in the rate of formation of either benign or malignant tumors. In other words, any chemical that is "oncogenic," in animals or humans. The great majority of chemicals characterized by EPA as potentially oncogenic in humans have been identified through animal rather than human studies.

The Delaney Clause's automatic zero-risk standard applies only to processed foods which concentrate. Our committee was asked whether this dichotomy between raw and processed food makes sense in light of our current knowledge?

The short answer to this question is "No." We can discover no scientific reasons for the law's different treatment of pesticide residues on raw versus processed foods. Strict adherence to the Delaney Clause, with the distinction between fresh and processed foods, would eliminate only about half of the potential oncogenic risk posed by 28 pesticides our committee studied intensively. In contrast, a uniform "negligible risk" standard representing no more than one additional case of cancer for every one million people exposed, would eliminate almost all of the potential dietary oncogenic risks posed by these residues.

We also found no reason to regulate new pesticides differently than old ones. According to our analysis, about 80 percent of the total potential oncogenic risk posed by 28 pesticides can be traced to pesticides registered before 1978, when EPA began requiring more rigorous tests. While the agency has strictly applied the Delaney Clause to pesticides registered after 1978, it has yet to apply it to those approved earlier.

In reaching these conclusions, we relied on information provided by EPA on the oncogenic potential of 28 pesticides, food consumption patterns, and current pesticide tolerances. We calculated that most of the potential risk posed by these chemicals, appears to be concentrated in a small number of foods and pesticides. About 80 percent of the potential oncogenic risk from the 28 compounds we studied is associated with the residues of 10 compounds in 15 foods.

Our analysis *assumes* that pesticide residues are present in foods at their legal maximum levels. We do not believe this is true for the great majority of foods, but data on actual residue levels present in foods as eaten are limited. Moreover, we were asked to look at levels of pesticide residues *allowed* under current federal laws and regulations. The key word here is "allowed." We were not asked to determine "actual" oncogenic risks posed by pesticide residues. Consequently, our findings do not show that any food is unsafe, nor should they prompt consumers to change their eating habits.

Given our finding that potential oncogenic risks are concentrated in a relatively few areas, we recommend that EPA identify and focus its regulatory effort on the most worrisome pesticides used on the most frequently eaten crops. The identification of crop/pesticide combinations posing the greatest potential oncogenic risks under current regulatory rules is useful as a priority-setting tool. By using this tool regulators can direct their efforts toward regulation of fresh and processed foods and of new and old pesticides on a more equal footing. We believe the specific foods and pesticides identified are less important than the overall theme, namely that a more consistent approach to setting pesticide residue tolerance levels is possible and needed.

We make a point in our report to note the special case of fungicides. While fungicides are critical for the economic production of many fruits and vegetables, almost all of these compounds are known to be oncogenic in laboratory animals and few effective alternative compounds are under development. Consequently, we recommended that EPA review these compounds simultaneously for each registered crop use and that it grant or retain tolerances for the combination of fungicides on a given crop that poses the lowest relative risk overall. The effect of this recommendation would be for EPA to examine fungicides as a class on a crop-by-crop use basis, rather than approving or rejecting individual fungicides one at a time, as is the case now.

Why, you may ask should consumers be asked to bear any risk of cancer from pesticide residues? If consistency is the problem, why not apply the strict zero-risk standard to both raw and processed foods? The answer is that such a policy would require that a large number of cost-effective pesticides be withdrawn from the market even though many of these compounds pose very low and possibly no actual human cancer risk.

Pesticides are essential to our agricultural productivity, controlling insect pests, weeds, and crop diseases. Non-chemical pest control strategies, such as biological control of pest species, may someday reduce the need for pesticides, but they are not yet available for many major crops. In the meantime, we cannot and should not jeopardize our goal of providing an adequate and economic food supply for the American public.

To recap, then, our committee examined the scientific basis for regulation of pesticide residues in foods. We found that the current law, which judges residues on raw foods by a less stringent standard than processed foods, is difficult to implement and does not provide the best protection of public health. In contrast, a uniform, "negligible risk" standard, applied across-the-board to old and new pesticides alike on both fresh and processed foods would virtually eliminate potential dietary oncogenic risks from pesticides. At the same time, such a standard diligently applied by EPA need not cause undue hardships for agriculture. By updating the Delaney Clause with such a uniform, negligible-risk standard, the EPA would be replacing the current crazy quilt of regulations with a pattern that is consistent, sensible, and scientific.

My colleagues and I will be happy to take your questions at this point.

The CHAIRMAN. Thank you very much, sir. And I also appreciate the testimony.

I mentioned at the beginning that I am very concerned about the report's findings. We should make it clear that it paints a worst case scenario, is that correct?

Mr. THORNTON. That is correct, sir.

The CHAIRMAN. And it could possibly overstate some of the risks involved.

Mr. THORNTON. It magnifies. It uses a publicly available list of tolerances and "Q" stars which has the effect of establishing a magnified example of risks. But what we were trying to do was examine the legally allowable level of risk that would allow a regulatory agency to come in and identify the areas of concern and to do the definitive studies that would be required.

The CHAIRMAN. Now, you spoke of oncogenic chemicals, those that create tumors?

Mr. THORNTON. Yes, sir.

The CHAIRMAN. Now, there is a list of 53 that the EPA knows are oncogenic. You didn't evaluate the whole list, is that correct?

Mr. THORNTON. No, sir. We evaluated 28 of the 53 because EPA provided us with oncogenic potency estimates—or Q stars—only for those 28 pesticides.

The CHAIRMAN. Does EPA have existing data on some of the others?

Mr. SHORNTON. They have some kf the data, but they did not have sufficient data for us to use them in our report.

Don, Don Bissing.

Dr. BISSING. That's right. We used the 28 compounds for which "Q" star was available.

The CHAIRMAN. Is it true that only 12 pesticides are responsible for 90 percent of the cancer risk posed by the 28 chemicals studied?

Mr. THORNTON. Mr. Chairman, that makes the assumption that the document itself is an assessment of actual risk. We, of course, can only say that based on the total risk figures that were developed by this computation, those substances are identified. It would be correct that those are the pesticides which should be looked at first. But the risks set out by those particular substances should not be considered as actual risks.

The CHAIRMAN. But what percentage of the total cancer risk from pesticides would you say these 12 chemicals pose? More than half?

Mr. THORNTON. Indeed. Art Upton, let me refer to Art for that question.

Dr. UPTON. That's correct.

The CHAIRMAN. We will be asked this question by everyone, so let me ask you, does the Academy report recommend the repeal of the Delaney Clause?

Mr. THORNTON. No, sir. It does not. We did not attempt to study the legal methods that might be used to arrive at a uniform negligible risk. There might be other ways of accomplishing that goal: congressional review, congressional language, the possibility of changes in rules with successful review by the courts, all of these are possible.

Let me refer to Richard Merrill.

Mr. MERRILL. I would just add one thing to what Chairman Thornton said. There is a lawsuit currently pending in the District of Columbia Court of Appeals which seeks to——

Senator PRYOR. Would you bring the mike closer? Thank you, sir.

Mr. MERRILL. Yes. There is a lawsuit currently pending in the Court of Appeals for the District of Columbia Circuit which challenges FDA's recent negligible risk interpretation of the Delaney Clause. It is fiercely contested and it is a close case.

Should the FDA prevail in that lawsuit, the language of the Delaney Clause will take on a flexibility that would, it seems to me, permit the EPA to follow in line.

We knew that this lawsuit was pending, and we thought it inappropriate to try to address the merits of the dispute that is being fought out by two well-represented parties.

The CHAIRMAN. Well, your report advocates a negligible risk standard which you referred to as a one in a million risk.

Isn't the problem not so much the standard that EPA is applying, but that EPA sometimes has been unwilling or even unable to remove old pesticides from the market?

Mr. THORNTON. EPA is faced with most difficult decisions and enormous volume of work to be done. Indeed, I think that that may be one of the reasons that the EPA asked this committee to come into existence, in order to seek to advise as to how a more rational even-handed system of regulation could be arrived at in order to effectuate that goal.

The CHAIRMAN. Well, the reason I asked is that your report says that a negligible risk standard, if consistently applied, could lead to elimination of up to 98 percent.

Mr. THORNTON. Yes, sir.

The CHAIRMAN. Ninety-eight percent of existing dietary risks from exposure to oncogenic pesticides; now that assumes a negligible risk standard. I want to make sure that I am correct on this. It's not a risk/benefit standard.

Mr. THORNTON. Yes, sir.

The CHAIRMAN. That would be a major departure from current FIFRA standards for raw commodities, would it not?

Mr. THORNTON. Yes, sir, it would.

The CHAIRMAN. Are you urging us to do that?

Mr. THORNTON. We are urging that consideration be given to a minimal risk program because we think that will enhance the public health. The FIFRA legislation does have benefits considered as well as the risk, and most of the committee members advocate that some consideration be given with regard to the benefits which may be achieved as a negligible risk standard as adopted.

I believe Dick Merrill had a page in the report that referred to that conclusion.

Mr. MERRILL. Mr. Chairman, on page 14, we address the question, but perhaps not in as much length as we should, the role of benefits consideration. A first approximation of the chemicals to be addressed is performed using the negligible risk standard, which is a tool for target identification from our perspective. As those risk estimates are verified, we would expect, as the current law permits, to address the question of whether or not the benefits of a compound that exceeds risk level warrant its continued registration or continued use for a particular commodity because, for example, there is nothing else available to protect that commodity in that region of the country.

The CHAIRMAN. In reading through this, and I am not a scientist by any estimation and I don't pretend to be, but I suspect I am like most consumers. You have to be concerned if you read the report. I don't think you could read it without being concerned.

You have got an audience here now. What would you tell consumers in response to this report? Are there certain foods that they should avoid?

Mr. THORNTON. No, sir. The report does not identify any specific foods as particularly hazardous. As we sought to evaluate the risk level of foods, we suggest a method of search and discovery of those areas that should be identified for careful review.

The CHAIRMAN. What about some of the subgroups that are more of a risk simply because of the way they consume food? Children consume more of these substances per kilogram body weight than adults, and if they were my children, they could bankrupt most Third World nations the way they eat.

Tell me, should the parents take special precautions?

Mr. THORNTON. Yes, sir. It is my understanding that our consumption estimates represent an average for the total population, ages 0 through 7. Art Upton.

Dr. UPTON. Yes.

Mr. THORNTON. So that has been taken into account in the maximum risk levels that are calculated here.

The CHAIRMAN. How quickly can EPA act?

Mr. THORNTON. The report suggests that efforts should be made to move into the area of developing this, hopefully, by the year 1990. I am not sure but what that is optimistic as a target time. But believing as we do that this would be a significant benefit to the American people, we would urge that it be accomplished as quickly as it can be done.

The CHAIRMAN. I thank you very much for your testimony. I am going to yield in just a moment to Senator Bond and to Senator Pryor.

Senator Pryor had mentioned to me, prior to your coming, of his high esteem for you, and I want to express my appreciation to you and to the panel. This is a difficult area. It is not a glamorous area in any way. But I can think of very few things that are more important to all of us, no matter where we live in the country. I extend my appreciation for the enormous amount of time that all of you and the National Academy have taken on this.

Mr. THORNTON. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Bond.

Senator BOND. Thank you, Mr. Chairman.

First, with your permission, I would like to submit, for the record, a statement made by Congressman Pat Roberts which he has asked be included as part of the record.

The CHAIRMAN. Without objection, so ordered.

[The prepared statement of Hon. Pat Roberts, a Representative in Congress from the Second District of Kansas, follows:]

TESTIMONY OF
THE HONORABLE PAT ROBERTS

RANKING MINORITY MEMBER

THE SUBCOMMITTEE ON DEPARTMENT
OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE

THE HOUSE COMMITTEE ON AGRICULTURE

MAY 20, 1987

BEFORE THE
SENATE COMMITTEE ON AGRICULTURE,
NUTRITION, AND FORESTRY

Mr. Chairman. As you know, I have for some time now had a keen interest in the matter of pesticide residues in food, and more broadly the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). So, I view this opportunity to speak to the Committee on pesticide residues as both a pleasure and an honor.

One statement from the report, Regulating Pesticides in Food: the Delaney Paradox, has the distinction of being both most readily understandable to the layman, and useful to the serious policymaker: "Logic argues that the EPA should focus its energies on reducing risk from the most-worrisome pesticides on the most-consumed crops . . . ," (p.14). The Environmental Protection Agency (EPA), must exercise a vitally important mandate with limited resources. Given this reality, I cannot insist strongly enough the need for EPA to review thoroughly, with a receptive eye, the suggestions embodied in the Delaney Paradox.

As a member of the Committee on Agriculture, and ranking minority member of the SubcomMittee on Department Operations, Research and Foreign Agriculture (DORFA), I fully appreciate the enormity of the task that EPA has in administering the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) -- it's immensely complex, resource intensive, and vitally important to the well being of the public. When it comes to the matter of pesticide residues in food, I can honestly say that throughout my experience with FIFRA, no other issue provokes a more visceral response in people.

We must not let, the exercise of emotion, and frustration and controversy translate into real setbacks for advancing the protection of the public from overexposure to pesticide residues.

The Delaney Paradox report suggests that we work to regulate the most worrisome chemicals -- in one case, a group of fungicides that appear to present a pressing oncogenic threat. To accomplish this aim, the National Academy of Sciences (NAS) report states that, "A uniform negligible-risk standard could give the EPA the flexibility needed to reduce dietary oncogenic risk over time," (p.13). The report goes on to suggest that due to the lack of flexibility mandated by the Delaney Clause, EPA has not been able to grant tolerances for new chemicals that would reduce the exposure of the American public to the risk of oncogens. In fact, the Delaney Clause has hindered the move away from high risk products toward low risk chemicals.

Because EPA's regulatory ability to discriminate between high risk and low risk oncogens is hindered, there is a costly diffusion of scarce resources. The Delaney Paradox report clearly indicates that approaching the regulation of oncogenic risk from a position of absolutism, may not conform to our "real world" needs. This whole process of regulating pesticide residues in food is extremely complex, and even more so for fungicides, but it is clear that the Delaney Clause doesn't assist EPA in its task. In fact, the NAS report states, "It is the committee's view that literal application of the Delaney Clause will significantly complicate the EPA's efforts to reduce dietary oncogenic risks from fungicides," (p. 8).

One of the most important considerations for EPA today is the furtherance of its credibility as an effective regulator. The Agency can best enhance its credibility by approaching the regulation of pesticides from a "real world" approach. This "real world" approach is a logic that the American public can trust, and is suggested by the NAS report -- that the most threatening pesticides deserve the most scrutiny from EPA.

The NAS report finds that were EPA to regulate oncogens via a negligible-risk standard for raw and processed foods, the Agency could accomplish a 98 percent reduction in our current exposure to dietary risk from oncogens. This approach would win greater gains relative to a zero-risk regulatory posture for oncogenic residues in processed foods and their parent raw commodities. The report goes on to suggest that these relative benefits are achievable under the risk-benefit nature of FIFRA.

The linch-pin to this whole exercise, is the rate at which EPA can accomplish the task of reregistering older chemicals, the sequence to be followed, and the calculation of risks versus benefits. Congress could immediately assist EPA in its work by passing the FIFRA bill of last October. The FIFRA bill that the House passed three times last year, once by unanimous consent, constitutes a level of reasonableness that I have rarely seen in such a controversial piece of legislation.

Any discussion of pesticide residues in food must recognize the need to shore up the public's confidence in our nation's food supply. Some have insisted that the fifty individual states should have the discretion to initiate tolerance standards independent of EPA. This policy stance would be most cumbersome and would not encourage the public's confidence in the wholesomeness of our food.

The most effective means for satisfying public concern for the integrity of our food supply is to mandate uniform marketing standards for pesticide residues. To accomplish this we must permit EPA to operate unfettered by excessive constraints -- I think the FIFRA bill of last October does this. To understand why many oppose uniform marketing standards for pesticide residues, we need to examine the strategy involved in letting certain states set their own standards.

Not all states have the wherewithal to set responsible tolerance standards independent of EPA, however, some states -- usually the larger ones -- can reach persuasive conclusions regarding appropriate levels of pesticides residues. If a group of people believe that an EPA tolerance standard is inadequate and they fail to convince EPA of the merits of their concern, they can pursue an independent tolerance standard at the state level. If they succeed in establishing a more stringent tolerance standard at the state level, then they succeed in creating a two tiered standard. The practical effects of this plurality of standards are two-fold. First, the marketing impact for both farmers and businesses is crucial and substantial; and secondly, the confusion and controversy can severely strain the public's confidence in the wholesomeness of our food. This unstable atmosphere forces EPA to act hastily, and the benefits of such action may not be clearly calculated.

Even the most casual examination of this report provides the reader the basis for understanding the desirability of strong FIFRA legislation. The compromise FIFRA bill of last October is precisely the kind of legislation that can address the report's stated need for reregistering many older chemicals. Essential to any quickening of the reregistration pace is the attendant need for more resources at EPA.

On April 7, the DORFA Subcommittee of the House Committee on Agriculture, heard testimony from Dr. Jack Moore, Assistant Administrator for Pesticides and Toxic Substances for EPA. Dr. Moore clearly outlined the dilemma facing the agency. The agency's Office of Pesticide Programs is forced to weigh the benefits of allocating time and resources between registering new pesticides or reregistering older chemicals. If you emphasize the review of older pesticides for safety, at the cost of shifting resources from the registration process, then potentially you delay the introduction of new pesticides which may be less toxic to man and our environment. However, the reregistration of older pesticides is also a crucial task because you may have some real "bad actors" out there that need to be taken off the market. Clearly, adequate funding for both activities is most desirable.

In 1970 Congress established the primacy of EPA as a leading agency for the protection of our environment and health. I encourage the thoughtful continuation of this mandate, and a strong FIFRA bill will do this. Rather than permit a plurality of pesticide residue standards, we need to firmly position EPA as the nation's highest authority for setting pesticide residue standards -- and then concentrate our resources there. The crux of the matter is the idea that we need to commit the best science available towards ensuring the integrity of our nation's food.

Senator **Bond**. Congressman Roberts has been active in this area for a long time, and I think his prepared statement reacts specifically to this report and I believe it can be a helpful addition to the record.

President Thornton, we appreciate very much the thoughtful approach that you have taken. It has been some time since, as a lawyer, I had the opportunity to explore the scientific implications of the Delaney Clause. But, as I recall, talking to scientists and medical doctors at the time, they felt that there were many instances where an absolute standard applied, as the Delaney Clause does, to certain man-made additives tended to divert attention away from other dangers.

Is this essentially what this distinguished body is telling us today, that you can't expect absolutes in nature?

Mr. **Thornton**. We have come to the conclusion that there is no scientific basis for distinguishing between raw and processed foods in the application of any regulatory standard. Indeed, in doing this the Delaney Clause, as we report in the report, has caused some very difficult and unfortunate things to happen. A new chemical was seeking registration for hops which concentrated in dried hops. That new chemical was tested and discovered to have an oncogenic potential of about 1 case in 100 million, or 10 to the minus 8. That chemical was rejected for that use due to the Delaney Clause, even though an old chemical in use on hops has a much higher potential oncogenic risk level, on the order of 1 in 100,000.

So the American public was deprived of an opportunity to significantly improve the health standard on that particular application because of the Delaney Clause prohibiting a new material which, as I said, had a potential of 1 case in 100 million.

Senator **Bond**. I recall having worked with doctors whose responsibility was to treat diabetic children, and they fought a battle over saccharine, at which time some of the rat tests, or the animal tests, created a great deal of public scorn because of the high concentrations. I think that your efforts to focus public concern on standards of risk is admirable.

Following up on the chairman's comments about risks to children, my 6-year old is a major consumer of peanut butter. If I recall correctly, Dr. Upton, aflatoxin is an oncogen that occurs naturally in peanuts?

Dr. **Upton**. That's correct, Mr. Bond. Aflatoxin is a mold product, and any foodstuffs that are allowed to stand around in moist warm climates get moldy—we know that. Aflatoxin is one of the mold products that may be produced, and it is a potent carcinogen in laboratory animals. The epidemiological evidence suggests that it is an important cause of liver cancer in parts of the world, especially tropical areas, where stored food does get moldy.

Senator **Bond**. So it is possible that perhaps a fungicide, which would be banned under the Delaney Clause, could in fact make peanuts, peanut butter safer by reducing a more serious risk from aflatoxin? Is that a——

Dr. **Upton**. Indeed that is a plausible tradeoff. And it's that kind of risk-benefit calculus that is so important, I think, in sound regulatory policy.

Senator Boren. As I understand, you are telling us that we have focused too narrowly and with too much absolute certainty on one small area, whereas we should have been expanding our concern and applying negligible risk standards across the board to a wide variety of commodities, raw as well as processed.

Are there efforts underway in EPA to improve the collection of data on the actual residue levels present in food?

You have indicated that you have just been examining the maximum tolerance levels. What is the status of examination as to the oncogenic potential in foods we are actually consuming?

Mr. Thornton. May I refer that to Don Bissing?

Dr. Bissing. There is a massive effort going on within the EPA, as well as within the food processing industry, and the agricultural chemicals industry, in trying to put the actual residue crop protection chemical residue into perspective.

Reregistration process of EPA, as going on, will furnish a great deal of that data. I think we will find that tolerance levels set for old chemicals are much higher than they need to be based on actual residue data.

Senator Boren. Would you explain what you mean by the tolerance?

Dr. Bissing. The tolerance is the residue level allowed on a food crop as it leaves the farm gate. Tolerance levels are set based on the highest level found in residue studies. Those studies are done with maximum numbers of applications and maximum rates, which are seldom the case when crop protection chemicals are used.

So the anticipated residues would be much lower than the tolerance and, through processing, washing, and cleaning, as the food reaches the diet, we would expect those residues to be even lower than that.

I think that this is the reason the committee urges restraint on the part of the regulatory agency in dealing with this report, because we don't know enough yet about what actual residues are.

Senator Boren. I thank you for that very informative comment. I just hope that the coverage of this hearing carries that message because I expect we will see many reports that missed that important point. I thank you for having brought to our attention that important qualifier.

Mr. Chairman, I have exhausted my knowledge on this subject.

The Chairman. Thank you, Senator Pryor.

Senator Pryor. Mr. Chairman, the second weekend in June of each year, President Thornton and I and every other politician, public official and public servant in Arkansas, make an annual trek down to Bradley County, Ark., the tomato capital of the world.

Now, President Thornton and I are going down there in the second week of June. We are going to be in a parade, and somebody is going to come out of that parade crowd, and they are going to say, what about this report that you fellows have been listening to up there in Washington that puts tomatoes—I am afraid it will be interpreted this way—very high in the risk category? For example, table 3-23.

We have not only the parade, Mr. Chairman, we have a tomato eating contest out on the courthouse lawn. [Laughter.]

The CHAIRMAN. [illegible] [Laughter.]

[illegible]

Senator [illegible]. [illegible] [Laughter.]

[illegible] Mr. Chairman. [illegible]

[illegible]

The CHAIRMAN. [illegible] [Laughter.]

Senator [illegible]. [illegible]

Mr. [illegible]

Mr. [illegible]. [illegible]

[illegible]

[illegible]

Senator [illegible]. [illegible]

Mr. [illegible]. [illegible]

Senator [illegible]. [illegible]

Mr. [illegible]. [illegible]

Senator [illegible]. Thank you, [illegible]

The CHAIRMAN. [illegible]

Senator [illegible]. [illegible] Mr. Chairman. [illegible]

The CHAIRMAN. [illegible]

Mr. [illegible]. [illegible]

The CHAIRMAN. Thank you.

Senator [illegible].

Senator [illegible]. Thank you, Mr. Chairman.

Mr. [illegible]

cerned that there be some equity as well as protection for the American consumer and equity for the grower as it relates to imported foodstuffs.

In the course of preparing that legislation, my office did a little research. They contacted the Los Angeles Inspection Office of the Food and Drug Administration which, of course, has the responsibility for enforcing the tolerances that EPA has set. After speaking with the Los Angeles FDA inspectors, we were surprised to learn that they could not cite a single example where, in their inspections, they had found a serious potential health risk being posed to consumers from the consumption of either domestic or imported produce inspected at the L.A. laboratory.

I understand that FDA undertakes an inspection program and a random sampling of produce in supermarkets across the Nation, randomly selecting food items which are prepared and cooked presumably as they would be at home by the consumer.

FDA then, as I understand it, tests to determine whether or not the pesticide residues remaining on the prepared food, as it would be consumed, is below the daily dietary intake established by the World Health Organization.

Now, I am told that for the past 20 years the samples that they have taken and inspected have been consistently below this level.

Does that mean that we should view the Delaney Clause as a guide toward reducing the possibility of dietary risk of chemicals rather than as a measure of the safety of the present food supply? Is that a valid distinction?

Mr. THORNTON. I think you have fairly stated a valid distinction in that some of your discussion dealt with particular laws.

I would like to ask Dick Merrill to comment.

Mr. MERRILL. I don't think I have much to add to the chairman's statement. I think your characterization of the thrust of the report is correct.

I was, 10 years ago, general counsel of the Food and Drug Administration. It was their responsibility to monitor the food to see that the residues don't exceed those that are allowed by EPA.

What your episode demonstrates is that when we attempt to measure actual residues, we are going to confirm that the risk estimates that appear in the committee's report are probably exaggerated.

We will also discover that there are some areas where residues are higher than we would like them to be. And the whole purpose of the report is to enable EPA to address those.

Senator WILSON. So then I take it that the panel would agree that it is virtually impossible to ensure that no residue exists in a commodity. There is no such thing as no residue, and that the analytical methodologies that are currently available simply cannot test to absolute zero?

Mr. THORNTON. Yes, I think that is correct, sir. I agree.

Senator WILSON. So, what we are really concerned with here, in terms of protection of the consumer, is determining whether or not we have suitable criteria, an accurate criteria for acceptable risk?

Mr. THORNTON. Yes, sir, that is exactly correct.

Senator WILSON. In that connection, your report addresses what has been a distinction made between raw and processed foods. And you come to the conclusion that it doesn't much matter. What is important is the health risk, whether or not it is acceptable.

Mr. THORNTON. Yes, sir.

Senator WILSON. In that connection, dealing with raw produce, in the normal course of preparation by someone who goes to a supermarket, purchases food that has been subject to some pesticide or herbicide, brings it home, washes it and cooks it, what does that kind of ordinary and predictable processing do to the level of residue, as found, or would have been found by laboratory testing, had that same item been taken and tested immediately from the shelf or from the rack in the supermarket?

Mr. THORNTON. There is a very significant effect of the process you describe, and I would like to ask Don Bissing to elaborate upon it.

Dr. BISSING. Let me give you two examples. First of all is lettuce. As it comes from the field, tolerances are set before the removal of wrapper leaves, and that's a common practice in the field. At that point, a crop protection chemical may have a tolerance of 20 parts per million. Once the wrapper leaves are removed in the field, and residue levels tested, then we would typically see a reduction in residues down to two-tenths of a part per million.

Now, from there to the table, the situation is less clear. But certainly the grocer washes it, the user washes it, and further reduction of residues are certainly likely.

A very incisive study was done recently by Fermenta with their product, Bravo.

The CHAIRMAN. By whom?

Dr. BISSING. Fermenta. A product daconil or Bravo, which proved conclusively that what reaches the table is somewhere between 1 and 3 percent of tolerances. I think these are the kinds of studies that need to be done and data that need to be gathered by the food processing industry and by the National AgChem Association.

Senator WILSON. Between 1 and 3 percent of tolerance?

Dr. BISSING. Of the tolerance.

Senator WILSON. So what you are saying is that in our concern that we achieve acceptable levels of risk, there being no such thing as absolute zero, that what has been determined to be the tolerance for a particular pesticide is not even approached in that situation, in a typical situation?

Dr. BISSING. That's correct.

Senator WILSON. And you are saying that this is 1 to 3 percent?

Dr. BISSING. Of the tolerance.

Senator WILSON. And that is before it reaches the table?

Dr. BISSING. That's at the time it would reach the diet.

It is important to note that when the committee did its calculations, it assumed the each pesticide was used on 100 percent of the crop on which it had tolerances, and then all risks from all oncogenic pesticides were summed over that crop. A totally unrealistic situation from a standpoint of the real world.

Certainly market shares are never 100 percent. They never use all pesticides which are registered on a given crop. It's then, I think, critical for the Agency, as well as the industry itself, to determine what real residue levels we are seeing as crops enter the diet.

This way I think will help us to understand what the real risks are.

Senator WILSON. How much additional information do you think is required for you to be able to make that judgment?

Dr. BISSING. There's a lot of information out there already that simply needs to be gathered and analyzed. Additional information will have to be gathered. I can't say how much and how long that will take.

This way I think it will help us to understand what the real risks are.

Mr. THORNTON. Might I add, that indeed the committee's tables did magnify, as indicated, the levels of individual risk, and therefore it is not appropriate to use them for specific crops.

However, it spread a spectrum, it magnified and let us examine the effect of different regulatory devices in making the very real reduction in risk, which we can make because this is a controllable risk, by developing a sound, scientific method of applying the same negligible risk standard across that spectrum.

Senator WILSON. Let me ask another layman's question. Given what happens in the field, given what happens in the chain of distribution—you spoke of washing by the producer, and then washing by the grocer who finally markets the produce—how much of the risk that is involved, how much of that residue is removed by that process?

How much, then, would remain to be eliminated through the process of further washing by the cook, and actual cooking?

Dr. BISSING. That is a very difficult question to answer because it would depend entirely upon the chemical itself. I think, in general, we can say that residues in food are much, much lower than allowable tolerances, without being able to give you too many specific examples of residue reduction.

Senator WILSON. Thank you. Mr. Chairman, has the staff obtained a copy of the study that was mentioned as being incisive?

The CHAIRMAN. Yes; we do.

Senator WILSON. We do have that?

The CHAIRMAN. We do have some copies.

[The study is retained in the committee's file.]

The CHAIRMAN. I should also note that the record naturally will stay open for further questions and followup questions from the committee.

The Senator from South Dakota.

Senator DASCHLE. Thank you, Mr. Chairman.

Chairman Thornton, I think it is probably gratuitous that you are going to Arkansas tomato contest or tomato parade, because we have a cow-chip throwing contest coming up in South Dakota that could be a lot more problematic, given your chart.

[Laughter.]

Senator DASCHLE. Pages 78 and 79. I am troubled by, first, your answer to Senator Pryor, because it seems to be in direct conflict with what the statement is in describing the chart. Table 3-20 says, "Fifteen Foods with the Greatest Estimated Oncogenic Risk". Table 3-21: "Estimated Oncogenic Risk from Herbicides in Major Foods". And they rank them.

Now I do not know how more direct, and more blatant that could be, and I do not think your clarification before a few people of this committee is going to come anywhere near the clarification that may be necessary across the country.

I can just see the press releases and the reports coming out right now, that without the benefit of what little clarification you were able to make this morning, if I were a beef producer, a potato grower, a lettuce farmer, all the way down—in fact I look at all the crops you have listed here, and South Dakota is a pretty hazardous place for your health if this is the indication.

Pork, beef, corn, wheat, and there may be a chicken grower just calling in. But, you know——

Senator WILSON. Someone urging you not to go to lunch. [Laughter.]

Senator DASCHLE. That is right. Give us some assurance, that beyond this hearing, you are going to be able to clarify the very, very contentious charts that are listed. If I were anyone, going to a grocery store this morning, I would ask myself what do we eat, and I think that is the concern you have demonstrated here. I know it was well intended, and I applaud you for so much of the work that is included here.

But I think, as well intended as you are, you are basing these charts on what you indicate are theoretical risks, totally different than actual risks.

Mr. THORNTON. Right.

Senator DASCHLE. And that does not come out very well. What assurances can you give the American consumer, that what you have listed here ought not be as a great a concern, I mean, as the headline would indicate?

Mr. THORNTON. Well, for one thing, the items that lead the list tend to be those substances which are most regularly in the diet. The list is also affected by lifetime consumption patterns. And so lots of people eat tomatoes, and lots of people eat potatoes, and beef, and other things like that, and that causes them, in this theoretical construction that we have made, to rank very high.

However, they should be looked at by a careful risk assessment. We did put a footnote at the bottom of each——

Senator DASCHLE. Yes, but that is the problem, it is just a footnote.

Mr. THORNTON. Well, yes, but we put that footnote following every chart, and also in the discussion, and we have been very careful to emphasize it to members of the media, and to members of the public generally, that we were dealing with tolerance setting and not with the establishment of risks.

We do not have on our committee the expertise necessary to establish levels of risk nor the data to do so.

Senator DASCHLE. Well, why do you walk into a mine field, then, as you are doing, by putting on the pages of your report, charts which put in graphic display, and in order of oncogenic risk, the level of foods that are affected by your study?

Clearly, there is no emphasis here in the difference that one must make between theoretical and actual risk. For example, I am very particular to the beef question, and you could bring up pork or chicken, or wheat.

The linuron element in beef theoretically would put it second in the categories you have listed here, but you cannot find linuron in beef today. You cannot find it. It is not there. So if you take linuron out, beef is not even in the book.

And that is nowhere stated in your report. And I think you do a—as well-intended as you are—you do a real disservice, because I am for you, and I want to follow through with this. But why give the opposition a great big gift, in a sense, in blowing this whole thing out of the water, by saying all you are talking about is theoretical policy that has no relative statement in fact? That the actual risk, if you were going to list that on your charts, would be totally different than what you have got here.

Mr. THORNTON. We make that clear, because we did not have in our committee the resources of an EPA, to make the detailed studies that were required.

We used public figures. We magnified the level. We have stated, clearly, that we have magnified it, but the bottom line conclusion does remain, that a careful application of a uniform negligible risk standard will greatly benefit the public health.

Now, why did we not just leave these charts out of our book? The problem there is, were we to have done so, we would have been asked what was the basis for our conclusions? What did you use in order to reach these conclusions? And eventually, we would have revealed exactly what we used which was the construction of tolerances that we have available to us, and then it would look like we were trying to hide something, or hold it back.

That would have been far more serious than to present the material that we developed, straightforwardly, and to make the explanation that the risk levels shown here—and they are called the greatest estimated risk—and they are—said,

> These worst-case risk estimates are derived using data and methods described in the volume. They assume residues are at the tolerance level, although actual residues may be different.
>
> The numbers are the totals of the committee's upper-bound estimates of dietary oncogenic risk for oncogenic pesticides. As more accurate data are received by the EPA, crops may move, or off of the list.

Senator DASCHLE. Well, I think, Chairman Thornton, you are walking a fine line, and I do not want to criticize your effort here in total.

I mean, I think that there are a lot of good things that have come out of what you are suggesting here. I just wish it would have been rephrased and clarified in big, bold print.

Because I think what you are going to do is, you are going to cause hysteria, and you are going to give an opportunity to certain industries who are not on this list to say, look, you have a choice now: you can get cancer, or you can eat our food. And I think that is really unfortunate.

Mr. THORNTON. I hope that is not the result.

Senator DASCHLE. Well, I hope so, too, but I will go back to the office and I will bet you the first press release is going to be there.

Mr. THORNTON. We did wrestle, as a committee, with this most difficult question, and made the decision that I have indicated on the basis that it would be better to show our data as we present the report. Do any committee members have anything to add? Dick Merrill.

Mr. **Merrill**. If I may, Mr. Chairman. Senator Daschle puts his hand on what has been a central concern for members of the committee since we started this exercise.

One of the reasons that we had a dinner last night at the Academy for people interested in the report was to afford an opportunity to defuse potential misunderstanding.

One of the reasons for the press conference this morning, and one of the reasons why we welcomed the opportunity to come to this hearing, was to try to put our conclusions in perspective.

That is not to say we are going to be successful, but we are entirely in agreement with you that that table, which is the best data we had, should not be misconstrued, and we will try to help as much as we can to avoid that.

Senator **Daschle**. Well, I hope that we can assist in that effort.

The **Chairman**. I can think of one thing that should be noted here, and I do not want to exaggerate the problem, but I do not want to minimize it, either. While I do not want hysteria—none of us do—every time we have one of these hearings I usually decide that maybe I will just start fasting afterward, which probably would not be that bad of an idea. But while we will continue to eat our food, I think you do raise some very, very serious questions, and I do not think those should be minimized.

The report zeros in on some of the major regulatory problems you have at EPA. Let's just take one example: 4 of the top 12 high cancer risk pesticides are in a group called EBDC's.

Now, on page 89 of your report, there is a risk of 1 in a 1,000 attributed to EBDC's. That is 1,000 times greater risk than what the report says is an acceptable risk; 1,000 times greater. Now that is a problem we have.

About 9 out of the 10 most commonly used pesticides have not had a thorough enough study and testing to say that they are completely safe.

The budget of the EPA has been cut, and cut, and cut. Frankly—and this is my own opinion—I do not think that they have an adequate budget to take these dangerous pesticides off the market and dispose of them. I think that is why we find that 75 percent of the American people are instinctively concerned about pesticide residues in the food they buy.

Now, if 90 percent of the cancer risk could be averted by dealing effectively with 12 compounds, then I think that is a matter of major concern for this country. I think it is a matter that requires EPA and others to find out how we deal with those 12 compounds, and, if necessary, remove them and find alternatives, but even in finding alternatives, I believe we have got to be able to do even better than we do now, and be able to do the scientific testing, do it adequately, accurately, and most important, quickly.

Would you agree with that?

Mr. **Thornton**. Mr. Chairman, I wish I could adopt as my own the words what you have just said. That was a fine statement, and I agree completely.

The **Chairman**. It is a real concern. I would say that I think this committee will handle it carefully, and I would hope dispassionately. I would hope that we could handle it in such a way as I believe you are also trying to do—as to ensure that we give an accurate picture, not a picture of hysteria.

Mr. **Thornton**. Yes, sir.

The **Chairman**. Are there other questions for the panel? Senator Pryor.

Senator **Pryor**. Mr. Chairman, if I might, I am going to lead to a question here. We are talking about how this story is going to play out there with the consumer and those who might not be in this meeting this morning, and I think Senator Daschle has really raised some very good points.

Here is a news release from the National Resources Defense Council, and I assume they are legitimate. [Laughter.]

It is based at 1350 New York Avenue, Washington, DC. Now I assume that this group feels that they have an obligation to, let's say, warn the public.

Here is what they say about your report, and I am quoting from their third paragraph.

It says:

> The NAS report reveals high cancer risks from widely used pesticides which are consumed with many common foods such as tomatoes—remember, 2 weeks from now, Ray—beef, potatoes, oranges, lettuce, and apples. The NAS concludes that 60 percent of herbicides, 30 percent of insecticides, and 90 percent of fungicides have the potential to cause cancer.

And then the follow-on paragraph: "Under the current statute, we cannot trust the Federal Government to protect our food supply from dangerous chemicals," said Janet Hathaway, the staff attorney.

Now, would that be the interpretation of this distinguished committee as to what this report says? Ray, you may want to let your colleagues——

Mr. **Thornton**. I think my colleagues——

The **Chairman**. We are speaking of your distinguished committee, not ours.

Mr. **Thornton** [continuing]. Might join me in saying no to that—whether that is a fair characterization of our report.

Senator **Pryor**. Doctor, did you——

Mr. **Merrill**. I agree with the chairman.

Senator **Pryor**. All right. Then I will just ask this one question because, Mr. Chairman, President Thornton, in addition to all the other things I said he did, is also an author.

He has been a journalist, and in fact, if you were a journalist today, President Thornton, and you had *x* number of inches to write a headline, how would you headline this particular report? What would be the headline tomorrow in the New York Times or the Washington Post, or the Arkansas Gazette about this report?

Mr. **Thornton**. The National Academy of Sciences today released a report addressed to the Government, in particular, the EPA, which is presently faced with a crazy-quilt pattern of——

Senator **Pryor**. That is a long headline. [Laughter.]

Mr. **Thornton**. And the report does not address actual exposure to pesticide residues, nor does it comment on the safety of individual foods. It does not suggest any change in eating habits.

However, the report points out ways, a method by which the EPA could increase the safety of our foods by using a negligible risk standard applied uniformly to all foods. That is what I would write.

Senator PRYOR. Thank you.

The CHAIRMAN. One newspaper report reads: "Bugs, People, Bad Time in USA", and I am not going to say which newspaper.

Gentlemen, thank you very, very much for your testimony, and I expect that there will be a number of followup questions. I think you have done a great service for all of us, and I appreciate it very much. Thank you.

Our next witness is John A. Moore, the Assistant Administrator for Pesticides and Toxic Substances from EPA. It is good to have you here, sir. I would like you to take that center table so everybody can take a shot at you, and Senator Pryor says you, too, are welcome to come down 2 weeks from now to the tomato parade, if you would like to.

STATEMENT OF JOHN A. MOORE, DVM, ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Dr. MOORE. Senator, that offer sounds better than Senator Daschle's, given the nature of the festivities.

Senator, I have a long statement that I would ask be inserted for the record.

The CHAIRMAN. I would appreciate that because we have had to change our normal starting time, and we are running into time restraints, and I would appreciate that.

Dr. MOORE. Fine. I would like to summarize a few thoughts, many of which I think were covered in the dialog that you had with the Academy committee members just a few minutes ago.

Registration under FIFRA authorizes the sale of a pesticide for use on a specific crop under specific conditions. A tolerance, under the Federal Food, Drug, and Cosmetic Act, on the other hand, makes it lawful for food to contain pesticide residues up to a stated limit.

Tolerances are intended to be enforcement tools to legitimatize registered applications of pesticides. Tolerances are generally established using a combination of assumptions which are not intended to reflect actual residues in the ready-to-eat food supply.

For this reason, it is necessary to draw a distinction between tolerance levels and the set of assumptions on which they are based, and dietary risk assessment from the intake of pesticide residues in or on the foods we eat.

In general, the data required to support a tolerance petition are of two kinds: residue chemistry data and toxicology study results of various types. All of these data requirements are designed to answer three key questions. First, what is the chemical residue? Second, how much residue is there? The what, and how much information derived from residue chemistry data, is then used by EPA toxicologists to answer the third question: does the residue represent an acceptable dietary level of exposure? In other words, is there a practical certainty that under the prescribed conditions of use of the pesticide, no unreasonable adverse effect will result in humans even after a lifetime of exposure?

Traditionally, in making tolerance decisions, EPA has compared the amount that you may consume based on toxicology data with the theoretical maximum residue contribution, TMRC, if you will, of the pesticide to the daily diet. I want to draw attention to the first two words in that phrase, TMRC, theoretical maximum. The TMRC is a mathematical construct obtained when the proposed tolerances are summed together with any other tolerances, such as on other foods, that have already been established for the pesticide. That TMRC reflects assumptions that one, 100 percent of the crops that may legally be treated with a pesticide are in fact treated with the pesticide, using maximum application rates and allowing only the minimum preharvest interval following the final treatment, and two, residues in commodities that may be treated with the pesticide are always present at tolerance levels at the time of consumption. These are rather conservative assumptions.

I would like to use a few examples to cast some perspective on TMRC assumptions as compared to actual pesticide usage and residue data analyses that the Agency has. If I could have that first chart.

The chart [chart 1] here is depicting actual data of a pesticide that is a potato sprout inhibitor called chlorpropham. Based on postharvest residue data from an efficacy study, the chart shows the distribution of residue levels in treated potatoes sampled during storage. On the horizontal axis, residue values range from 0 to 50 parts per million [ppm]. The vertical bars show the frequency with which these residue values were detected in a total of over 2,000 samples.

Now if we put the first overlay on this chart, it shows the established tolerance for chlorpropham residues in potatoes which is 50 parts per million. Note, if you will, that the great majority of residues are far below that 50 parts per million; however, there is one outlier, if you will, that comes comparatively closer to, but does not quite reach that 50 parts per million. Tolerances are traditionally set to accommodate such outliers in residue data, and this data set confirms 50 parts per million as that appropriate tolerance level for chlorpropham in potatoes.

The second overlay to chart 1 shows the average residue level based on that same data set. If we were to calculate average potential dietary exposure to chlorpropham from potato consumption, the anticipated residue level would be 2 parts per million, certainly a marked contrast to the TMRC assumption of 50 parts per million.

The third overlay on this chart shows the 95th percentile of residue levels in potatoes. In other words, that range in which 95 percent of all the values would be found. This would represent a more conservative estimate of anticipated residue levels for dietary exposure assessment purposes. However, this more conservative approach, compared to just taking the average, is still in marked contrast to the 50 part per million tolerance level.

Now let me switch to food commodities as opposed to just tolerance per se. The next chart [chart 2] shows that in using the TMRC concept to estimate dietary exposure and risk from total pesticide residues that may occur in any given type of food commodity, one necessarily assumes that each commodity contains tolerance level residues of each and every pesticide that may be legally used on that commodity.

I think it is safe to say that this is never the case. If we consider the commodity, tomatoes, tolerances have been established by EPA for 92 pesticides which may be legally used on tomatoes.

This chart [chart 3] shows an overview of these various breakouts of registered use: 54 insecticides, 20 fungicides, 7 herbicides, et cetera.

Theoretically, they all could be on any given crop of tomatoes. In reality this is unlikely to occur. By comparison, the next chart [chart 4], showing recent pesticide usage data on tomatoes grown for processing in the State of California, which produces some 86 percent of tomatoes grown for processing in the United States. California processing tomatoes for the 1986 year were actually treated with very few of these 92 pesticides.

As you can see here, 23 percent of those farms use no fungicides; 48 percent used one fungicide; and roughly 26 percent used two fungicides, and then 3 percent used three. Nothing approached, obviously, the 20 applications of all materials that are possible.

Let me now focus for a moment on the 20 fungicides that are registered for use on tomatoes, as previously shown in chart 3. Of these 20 fungicides, 13 have been shown to be oncogenic in test animals. However, according to the California survey, only 2 of these oncogenic fungicides were reportedly used on tomatoes destined for processing: 39 percent of California farms reported use of chlorothalonil as the material of choice.

If we now look at residue data on chlorothalonil [chart 5], and if you let my data base still be tomatoes, but now be fresh tomatoes as opposed to processed tomatoes, I have depicted here the results of four recent studies, two conducted in California and two in Florida, designed to evaluate the potential residues of chlorothalonil in fresh tomatoes as they leave the field, and as they are eaten. The established tolerance for chlorothalonil on tomatoes is 5 parts per million, indicated by that leftmost vertical bar. All postharvest farm gate residues in tomatoes in these studies were below 5 parts per million.

In order to evaluate the effects of processing on residue levels between the farm gate and consumption, residues were measured not only immediately postharvest, but also as tomatoes left the packinghouse and as they were marketed in stores or restaurants.

The chart [chart 5] shows the effect of each of these steps on residue levels. There was little or no detectable residue of chlorothalonil in tomatoes by the time that commodity reached the consumer. In fact, 95 percent of the residues were removed during washing at the packinghouse. I might also say that if these were the same pesticide used on tomatoes going into a processing plant, this early washing step would also have removed the majority of the material.

For the majority of existing pesticides, EPA does not currently have the kind of detailed information on what happens to residues between the farm gate and the consumer that we do have, for example, on the chlorothalonil for tomatoes. My point in these examples is that the use of theoretical maximum residue contribution

[TMRC] assumptions to estimate dietary exposure and risk almost always overstates substantially the potential risk to consumers from pesticide residues in the food supply. For this reason, EPA's current thinking on the use of TMRC assumptions for risk assessment purposes is that the TMRC approach represents a useful sorting tool for determining regulatory priorities in the absence of real data on usage and anticipated residue levels for a great many existing pesticides. However, the TMRC approach cannot give us definitive answers concerning the actual risks associated with agricultural uses of specific pesticides.

In those instances where that TMRC calculation suggests a concern, EPA needs to receive data like those that I have just used in these illustrations on tomatoes and potatoes, in order to make an informed data base oriented decision.

The examples that I have used also illustrate some types of data analyses that can be conducted using the technical capabilities of EPA's newly computerized Tolerance Assessment System [TAS].

The Tolerance Assessment System is potentially a very powerful analytical tool for calculating dietary exposure, estimating risk, and predicting impact of hypothetical decisions. The TAS, if you will, can go considerably beyond the traditional TMRC approach to dietary risk. TAS can be used to estimate pesticide residue intake levels, not just for the population as an average, but also for some 22 subgroups, including several ethnic and age groups which includes infants, as well as pregnant women and nursing mothers. The system can also be used to differentiate overall consumption patterns by season and region.

TAS may be used to calculate, where verifiable data are available on the actual percentile distribution as you go into the processing of various foods as well.

I think we are finally reaching the stage of being able to manage the process, using such types of systems and such data, in a way that we can have data available for informed decisions.

[The prepared statement of Dr. Moore follows:]

STATEMENT OF
JOHN A. MOORE
ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
U.S. SENATE

MAY 20, 1987

Good morning, Mr. Chairman and members of the Committee. Last month, in testifying before a subcommittee of the House Committee on Agriculture, I cited pesticide tolerances as a regulatory issue which has assumed greater significance since last year's deliberations on reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Today, I welcome the opportunity to discuss EPA's tolerance process in the overall context of the Agency's regulatory responsibilities under the interrelated authorities of FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA).

EPA must make FFDCA tolerance decisions (maximum legal residues) in conjunction with pesticide registration decisions under FIFRA. If a pesticide is to be registered under FIFRA for use on a food or animal feed crop, a tolerance, which specifies an upper limit of allowable residues, must also be established under FFDCA. In some cases, an exemption from the requirement of a tolerance may be granted, but only where scientific data show that the total quantity of the pesticide residue on all treated commodities will present no hazard to public health. Tolerances for raw food and feed commodities are established under section 408 of FFDCA. Certain pesticide uses also require food additive tolerances under section 409 of FFDCA if: (1) the residues in processed commodities are concentrated to higher levels than the tolerance for the parent raw commodity, or (2) if the pesticide is actually added at some stage during food processing. FFDCA section 409, written in 1958, contains the "Delaney clause," which states that no chemical shall be deemed safe for the purpose of a food additive tolerance "if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

Registration under FIFRA authorizes the sale of a pesticide for use on a specific crop under specific conditions. A tolerance under FFDCA, on the other hand, makes it lawful for food to contain pesticide residues up to a stated limit. Pesticide tolerances established by EPA are enforced by the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and state enforcement agencies. Tolerances are intended to be enforcement tools and are set no higher than necessary to legitimize registered applications of pesticides.

Federal and state inspectors commonly sample food and feed produce for the purpose of tolerance enforcement soon after the farmer markets the treated commodity, so that any tolerance violations may be traced to their source. Tolerances are intended to apply to treated raw agricultural commodities as soon as they enter into commerce, starting when the produce leaves "the farm gate." In general, pesticide residues tend to dissipate or break down as time passes after harvest, and in the majority of cases, residues are further reduced by washing, peeling, cooking, and processing of foodstuffs. Almost by definition, tolerances represent levels of pesticide residue that are not expected to occur in food commodities that reach the consumer.

In fact, tolerance violations rarely occur in the form of "over tolerance" residues in food or feed produce at any point in commerce. Of the 2 to 4% of domestic food shipments that FDA typically finds to be in violation of tolerance requirements in any given year, the great majority of these violations indicate that a registered pesticide has been illegally used on an unapproved crop. For instance, Pesticide X is registered under FIFRA and has a tolerance under FFDCA for use on beans, but the farmer has used it on cabbage, so any residues on cabbage are illegal. Tolerance enforcement actions involving the seizure of tomatoes containing residues of the pesticide acephate are in this predominant category of tolerance violations. There is no tolerance for acephate in tomatoes, and no FIFRA registration for such use of acephate.

Tolerances are generally established using a combination of assumptions which are not intended to reflect actual residues in the ready-to-eat food supply. For this reason, it is necessary to draw a distinction between tolerance levels and the set of assumptions on which they are based, and dietary risk assessment from the intake of pesticide residues in or on the foods we eat. This distinction is one theme I want to emphasize and expand on in my testimony today.

Second, I want to describe some far-reaching regulatory implications of several related science policy issues EPA is now confronting. These include the set of issues that we asked the National Academy of Sciences to examine concerning the regulation of oncogenic pesticides, and issues that relate to the application of recent advances in our technical capabilities for dietary exposure and risk analysis. We must deal satisfactorily with these issues in order to proceed with the reassessment of existing tolerances for all previously registered agricultural pesticides subject to reregistration under FIFRA, and to achieve consistency in the standards applied to new and old pesticides.

In order to put today's issues in full perspective, the following portion of my prepared testimony describes the established framework of EPA's tolerance process, including the concepts and assumptions it has traditionally employed. The basic precepts of this system originated some 30 years ago, when the tolerance system for regulating pesticide residues in food and feedstuffs was first put into place.

THE TOLERANCE PROCESS: ITS BASIC FRAMEWORK

Tolerances are normally established as a result of a petition review process. The petitioner (usually the manufacturer of the pesticide in question) proposes to EPA a specific tolerance level for the crop(s) on which the product is to be applied. The petition must be supported by study results which satisfy the full spectrum of EPA's tolerance data requirements. These requirements are specified in the Agency's published regulations. EPA does not ordinarily generate any of the test data needed to establish a tolerance.

In general, the data required to support a tolerance petition are of two kinds: residue chemistry data and toxicology study results. All of these data requirements are designed to answer three key questions. First, what is the chemical residue? Second, how much residue is there? The "what" and "how much" information, derived from residue chemistry data, is then used by EPA toxicologists to answer the third question: does the residue represent an acceptable dietary level of exposure? In other words, is there a practical certainty that under the prescribed conditions of use of the pesticide, no unreasonable adverse effect will result in humans even after a lifetime of exposure?

Residue Chemistry Data

Residue chemistry data required for tolerance purposes includes several kinds of data ranging from "product chemistry" information to food processing study results.

Product Chemistry Data. The starting point in EPA's tolerance petition review process is the identification of the composition of the pesticide substance. EPA therefore requires composition data for pesticides, called product chemistry data.

In particular, these data include (1) information on the manufacturing process, (2) chemical analysis of the active ingredient, (3) "certified limits" for unavoidable variations in the amounts of the ingredients in a product, and (4) analytical methods used to determine the composition of the pesticide. Data on chemical composition and manufacturing processes are considered to be trade secret, confidential business information and EPA therefore does not release these data to the public.

EPA evaluates this product chemistry data set to determine whether impurities could consititute a significant component of the residue in food or animal feed. This is an important consideration because impurities created in the manufacture of a pesticide may become a residue problem, if they are not identified before tolerances are established. Dioxins and nitrosamines are probably the best known examples of significant impurities, but there are others. If an impurity occurs at a level that is toxicologically significant, a tolerance may be set for the impurity as well as for the active pesticide ingredient. Also, once problem impurities are identified by EPA, registrants can make adjustments to their manufacturing process or add purification steps to reduce the impurities to a safe level.

Metabolism in plants and animals. Plant metabolism data are required for tolerance purposes so that EPA may characterize the nature of the residue that occurs on crops intended for consumption as food or animal feed. To obtain this kind of data, the pesticide is labelled with a radioactive atom, usually ^{14}C, and applied to the crop plant in accordance with proposed use directions. Since the pesticide molecule is radiolabelled, any metabolite or degradation product remaining in the plant at maturity will be radioactive. The ^{14}C activity is separated into various fractions, and the chemicals associated with the activity are identified. It is very important to identify most of the radioactivity before tolerances are established. If this is not done, previously unidentified residues may become problematic in the future as more highly sensitive analytical methods are developed which could possibly detect residues of concern.

Plant metabolism studies are required for a minimum of three diverse crops -- for example, a root crop, an oilseed, and a leafy vegetable. If the metabolism in each of these crops is similar, then the metabolism in other crops is assumed to be similar. At the end of this process, EPA has enough information to answer the question, what is the residue in plants?

Whenever a proposed use of a pesticide may result in residues in animal feed, or when a pesticide is intended for treatment of livestock, animal metabolism studies are required in addition to plant metabolism data. Animal metabolism studies are generally carried out on ruminants (cows or goats) and poultry (chickens). Studies in swine may be required if a pesticide is applied directly to swine, or if the results from other animal metablism studies are inconsistent.

Like plant metabolism tests, animal metabolism studies use radiolabelled pesticides. The animals are dosed, and the level of radioactivity resulting in potential meat or poultry products (muscle, liver, kidney, milk, and eggs) is analyzed. If significant activity is found, then the chemical identity associated with the activity is determined. This process answers the question, what is the residue in animals?

Significant Metabolites and Tolerance Expression. Using the results of plant and animal·metabolism studies, EPA determines which metabolites are of concern and need to be included in the tolerance. In each case, this decision is based on (1) the toxicity of the metabolite, (2) the percent and magnitude of its residue, and (3) whether a practical analytical methodology is available or can be developed to detect and measure the metabolite. For metabolites that are toxicologically significant and occur at significant levels, a suitable analytical methodology is mandatory. Considered together, the pesticide active ingredient and any significant metabolites are called the "total toxic residue."

Residue Field Trial Data. Once the metabolism data have indicated what to look for, and methods have been developed to measure the total toxic residue, field experiments are carried out to answer the question, how much residue is there? These are studies in which the pesticide is applied to crops at known application rates, in a manner similar to the use directions which will eventually appear on the pesticide label if the tolerance and registration are approved. The field trial must reflect the use conditions that could lead to the highest possible residues. Generally this means the highest permissible application rate, the maximum number of applications allowed, and the shortest pre-harvest interval permitted by the use directions. Data are normally required for each crop or crop group for which a tolerance and registration is requested. In addition, data are also required for each raw agricultural commodity derived from the crop. As an example, for corn, residue analyses would be required for both grain and feed items -- forage, silage, and fodder.

Analytical Methods. Based on plant and animal metabolism study results, EPA requires petitioners to develop analytical methods to determine all components of the total toxic residue. In some cases, it is not possible to develop a single method that can determine all components of the residue, and several methods are required. Pesticide analytical methods are used for two purposes: (1) to obtain residue data on which dietary exposure assessments and tolerances are based, and (2) to enforce the tolerance after it is established. EPA validates each new analytical method using a method trial, to ensure that the procedures can actually be used for tolerance enforcement purposes by FDA, USDA, and state agencies. EPA also requires that enforcement methods do not involve reagents or equipment that is not commercially available to enforcement agencies, and do not take more than 24 hours per sample. After a tolerance is approved by EPA, the enforcement method(s) are published by FDA in its Pesticide Analytical Manual (PAM).

Determining the Tolerance Level. A petitioner for a tolerance proposes a tolerance level, based on residue field trial data, which reflects the maximum residue that may occur under "worst-case" conditions as a result of the proposed use of the pesticide. The tolerance must include significant metabolites and must be high enough to cover all components of the total toxic residue. If one component of the residue is significantly more toxic than other components, two levels may be included in the tolerance. For example, acephate tolerances are expressed as 3 parts per million (ppm) total residue, of which not more than 1 ppm is the metabolite, methamidophos. This was necessary because methamidophos is significantly more toxic than the parent compound acephate.

Processing data. While residue field trials provide data for estimating tolerance levels in raw agricultural commodities, processing studies are required to determine whether residues in raw commodities may be expected to degrade or concentrate during food processing. If residues do concentrate during processing, one or more food or feed additive tolerances must be established. However, if residues do not concentrate in processed commodities, the tolerance for the parent raw commodity applies to all processed food or feed derived from it.

Feeding Studies. Whenever pesticide residues result in feed items, data on the transfer of residues to meat, milk, poultry, and eggs are required. These studies are also required if a pesticide is to be applied directly to animals. In contrast to the animal metabolism studies I mentioned earlier, which are usually short-term, high-dose studies, these feeding studies are longer-term, low-dose studies designed to quantify the transfer of residues to meat, milk, poultry, and eggs. Usually three dose levels are used. The "1X" dosage is estimated by assuming tolerance level residues on the feed items involved, and from data on the percent of livestock diet represented by each feed item.

Two higher dosages, at "3X" and "10X," are also used, so that the feeding study will still be applicable if additional feed items requiring higher tolerances are needed in the future. In these feeding studies, animals are dosed for 30 days, or until residues plateau in milk and eggs. The animals are sacrificed soon after the last dosage, and the tissues used as food are analyzed for the parent compound and all significant metabolites. The resulting data tell EPA how much and what kind of secondary residues may result in meat, milk, poultry, and eggs, in cases where this question arises.

Toxicology Studies

For tolerance purposes, the toxicology data obtained from studies in which test animals are exposed to the pesticide chemical, mainly through oral exposure, are used to determine a "no observable effect level" (NOEL). The toxicological effects of concern here are not the severe and immediate poisoning symptoms that could result from accidental massive ingestion of a pesticide, or skin and eye irritation characteristics. Rather, these long-term feeding tests are designed to reveal potential adverse effects which may result from continuous low-level ingestion of a pesticide -- such as bone marrow damage, tumor induction, cancer, blood effects, and other chronic effects. Special test procedures also determine birth defect and gene damage potential. Using the NOEL, an acceptable daily intake (ADI) level can in most cases be proposed for humans by applying a suitable safety factor. The safety factor is intended to allow an extra margin of safety to compensate for (1) the scientific uncertainty inherent in the process of extrapolating human dietary risk projections from animal data, and (2) the possibility of special sensitivities to the pesticide in individuals among the general population. The magnitude of this factor may vary, depending on the toxicological effects observed in laboratory animals, and the amount of toxicity data available, but most tolerances for raw agricultural commodities have been established using a 100-fold safety factor.

Traditionally, in making tolerance decisions, EPA has compared the ADI with the Theoretical Maximum Residue Contribution (TMRC) of the pesticide to the daily diet. The TMRC is a mathematical construct obtained when the proposed tolerance(s) is summed together with any other tolerances that have already been established for the pesticide, and multiplied by average food consumption estimates based on USDA data from its Nationwide Survey of Food Consumption. In general, where basic data requirements are satisfied, EPA has found in favor of a proposed tolerance if the TMRC is less than the ADI.

There is an exception to this approach. EPA has not used the ADI concept, which implies a threshold level of risk, in considering tolerances for pesticides that induce cancer in test animals. The Agency does not approve food additive tolerances for such pesticides under section 409 of FFDCA, which contains the Delaney clause. However, EPA may set tolerances for raw agricultural commodities under FFDCA section 408 in cases where (1) the potential oncogenic risk is deemed to be low enough to be acceptable in light of the economic and social benefits to be derived from the agricultural use of the pesticide, and (2) residues do not concentrate to higher levels in any processed food derived from the parent raw commodity.

ACTUAL RESIDUES VERSUS THEORETICAL MAXIMUM RESIDUE CONTRIBUTION (TMRC)

I stated earlier that it is necessary to distinguish between tolerance levels and the set of conservative assumptions on which they are based, and dietary risk assessment for intake of pesticide residues in or on foods as eaten. For instance, the concept of the TMRC, which (as an index for comparison with an ADI) has traditionally determined tolerance decisions, reflects assumptions that (1) 100% of crops that may legally be treated with a pesticide are in fact treated with the pesticide, using maximum application rates and allowing only the minimum pre-harvest interval following the final treatment, and (2) residues in commodities that may be treated with the pesticide are always present at tolerance levels at the time of consumption. Let me also note in this context that the TMRC for a pesticide has also traditionally reflected a generalized "food factor." This food factor estimates consumption levels of particular food items in our diet.

At this point, I would like to use a few examples to cast some perspective on TMRC assumptions as compared to actual pesticide usage and residue data analyses in some specific instances.

Chart 1. This pesticide is a potato sprout inhibitor called chlorpropham. Based on post-harvest residue data from an efficacy study, the chart shows the distribution of residue levels in treated potatoes sampled during storage. On the horizontal axis, residue values range from zero to 50 parts per million (ppm). The vertical bars show the frequency with which these residue values were detected in a total of 2,007 samples.

The first overlay to this chart shows the established tolerance for chlorpropham residues in potatoes: 50 ppm. Note that the great majority of residues are far below 50 ppm; however, there is one "outlier" that comes comparatively closer to, but does not reach 50 ppm. Tolerances are traditionally set to accommodate such outliers in residue data, and this data set confirms 50 ppm as an appropriate tolerance level for clorpropham in potatoes.

The second overlay to Chart 1 shows the average residue level based on this data set. If we were to calculate average potential dietary exposure to chlorpropham from potato consumption, the anticipated residue level would be 2 ppm -- a marked contrast to the TMRC assumption of 50 ppm.

The third overlay shows the 95th percentile of residue levels in potatoes to be 10 ppm, which represents a more conservative estimate of anticipated residue levels for dietary exposure assessment purposes. However, this more conservative approach is still in marked contrast to the 50 ppm tolerance level.

Chart 2. As I have previously pointed out, tolerances are intended to apply to pesticide-treated commodities as soon as they leave "the farm gate" and enter commercial channels. However, for dietary exposure and risk assessment purposes, it makes sense to consider what happens to pesticide residue levels in food commodities during the storage and processing steps that intervene between the farm gate and actual consumption. Chart 2 shows three hypothetical pesticides for which residues either increase, decrease, or remain constant during processing and storage. In the majority of cases, residues decrease as indicated by the pattern drawn by the downward-sloping line on this chart. However, this depends on the chemical characteristics of the pesticide in question, and the nature of the processing steps. In cases where residues increase during processing, as indicated by the upward-sloping line tracing residue levels for one of these hypothetical chemicals, a food additive tolerance under FFDCA section 409 would be required.

Chart 3. In using the TMRC concept to estimate dietary exposure and risk from total pesticide residues that may occur on any given kind of food commodity, one necessarily assumes that each commodity contains tolerance-level residues of each and every pesticide that may legally be used on that commodity. I think it is safe to say that this is never the case. To illustrate this point, let's consider the commodity, tomatoes. Tolerances are established for 92 pesticides which may legally be used on tomatoes. Chart 3 shows an overview of pesticides registered for use on tomatoes, by type: 54 insecticides, 20 fungicides, 7 herbicides, 4 soil fumigants, and 3 growth regulators; plus 4 additional miscellaneous pesticides (not shown).

Chart 4. By comparison, Chart 4 shows recent pesticide usage data on tomatoes grown for processing in the State of California, which produces 86% of tomatoes grown for processing in the U.S. California processing tomatoes grown in 1986 were actually treated with very few of these 92 pesticides. Only 3% of California farms reported use of as many as 3 fungicides; 4% used as many as 4 herbicides; 4% used as many as 5 insecticides, 2% used 2 soil fumigants, and none used more than 1 growth regulator. The pesticide most frequently used was sulfur (on 64.4% of processing tomato production acreage).

I'd like to focus for a moment on the 20 fungicides registered for use on tomatoes, as previously shown in Chart 3. Of these 20 fungicides, 13 have been shown to be oncogenic in test animals. However, according to the California survey, only 2 of these oncogenic fungicides were reported used on tomatoes destined for processing: 39% of California farms reported use of chlorothalonil on tomatoes in 1986; 1% reported use of captafol. Captafol has since been voluntarily withdrawn from the market.

Chart 5 shows recent residue data on chlorothalonil. These are the results of 4 recent studies -- 2 conducted in California, and 2 in Florida -- designed to evaluate the potential residues of chlorothalonil in fresh tomatoes as they leave the field, and as they are eaten. The established tolerance for chlorothalonil on tomatoes is 5 ppm, indicated by the leftmost vertical bar. All post-harvest "farm gate" residues in tomatoes in these studies were below 5 ppm.

In order to evaluate the effects of processing on residue levels between the farm gate and consumption, residues were measured not only immediately post-harvest, but also as tomatoes left the packing house and as they were marketed in stores or restaurants. At the packing house, the tomatoes were washed, dried, and waxed. The tomatoes were subsequently transported to grocery stores or restaurants. The chart shows the effect of each of these steps on residue levels. There was little or no detectable residue of chlorothalonil in tomatoes by the time the commodity reached the consumer. In fact, 95% of residues were removed during washing at the packing house.

For the majority of existing pesticides, EPA does not currently have the kind of detailed data on what happens to residues between the "farm gate" and the consumer that we do have, for instance, on chlorothalonil for tomatoes. My point in these examples is that the use of TMRC assumptions to estimate dietary exposure and risk almost always overstates substantially the potential risk to consumers from pesticide residues in the food supply. For this reason, EPA's current thinking on the use of TMRC assumptions for risk assessment purposes is that the TMRC approach represents a useful sorting tool for determining regulatory priorities, in the absence of real data on usage and anticipated residue levels for a great many existing pesticides. However, the TMRC approach cannot give us definitive answers concerning the actual risks associated with agricultural uses of specific pesticides.

TOLERANCE ASSESSMENT SYSTEM ("TAS") ISSUES

The foregoing examples also serve as examples of some types of data analyses that can be conducted using the technical capabilities of EPA's newly computerized Tolerance Assessment System (TAS), where adequate usage and residue data are available. The TAS is now "on line," but it has not yet been fully implemented by EPA, pending the resolution of some important policy questions. The TAS is comprised of (1) data files (food consumption, toxicology, and residue data), and (2) software to access these data files, and to track EPA decisions regarding pesticide tolerances. The TAS is in fact the basis for the data system developed by the National Academy of Sciences in the course of conducting its study of oncogenic pesticides. As you know, the NAS report from this study, which was contracted by EPA in 1985, is being released today.

The TAS (and the NAS data system as an augmentation of the TAS) is potentially a very powerful analytical tool for calculating dietary exposure, estimating risk, and predicting impact of hypothetical decisions. The TAS can go considerably beyond the TMRC approach to dietary risk assessment; however, it can do so only in cases where adequate pesticide usage and residue data are available to replace TMRC assumptions.

The traditional TMRC approach used "food factor" consumption estimates for the U.S. population on a broad average, which were based on data from a 1965 USDA food consumption survey. The TAS taps into USDA's 1977-78 nationwide food consumption survey, which distinguishes dietary intake patterns among subgroups of the U.S. population. Based on this consumption data, the TAS can be used to estimate pesticide residue intake levels not just for the population as an average, but also for some 22 subgroups including several ethnic and age groups (including infants), as well as pregnant women and nursing mothers. The system can also be used to differentiate overall consumption patterns by season and by region.

One option offered by the TAS is the calculation of separate TMRCs for each of the 22 subgoups recognized by the system. Alternatively, TAS may be used to calculate an "Anticipated Residue Contribution" (ARC) where verifiable data are available on the actual percentile distribution of residues in treated crops; on the dissipation or concentration of residues during the storage, transport, and processing of food commodities; and/or on the percentage of a crop actually treated with a pesticide. Where appropriate, the TAS can also provide estimates of safe short-term dietary intake levels. This would be useful, for instance, where the toxic effect of concern is teratogenicity (potential birth defects) and an exposure level during certain weeks of pregnancy can be critical.

Before the TAS can become fully operational, however, it will be necessary for EPA to make decisions concerning several immediate policy issues. The Agency submitted the following issues for consideration at an open meeting of the FIFRA Scientific Advisory Panel (SAP) held this past March 27; the Panel was asked to provide guidance on the scientific criteria that EPA should consider in developing its policy in these areas --

(1) The use of subgroups. Regarding the TAS capability to estimate dietary exposure within separate subgroups of the U.S. population, the question arises: under what circumstances should tolerances be targeted to protect specific subgroups of the population, as opposed to the general population on a broad average? Here, the Panel commented in particular that the TAS is likely to overstate dietary risk to infants, and EPA should consider body surface rather than body weight comparisons with dietary intake levels for risk assessment purposes.

(2) Percentiles of exposure (risk). Since the TAS can be used to estimate the distribution of exposure to pesticide residues within a population, EPA must make a policy decision on the percentile of potential exposure to be used as the basis for regulatory decisions.

(3) Appropriate margins of safety. As noted earlier in my prepared testimony, a safety factor of 100 has traditionally been used to calculate an Acceptable Daily Intake (ADI) level for potential chronic effects that may be associated with a pesticide. However, in the past, safety factors were used in comparing the ADI to average consumption estimates. Here, the Panel specifically recommended that the use of the 100-fold

safety factor should be continued, and any modifications to this practice should be supported by scientifically defensible reasons.

(4) Anticipated residues and tolerances. Dietary exposure and risk assessments are directly dependent on residue estimates used in the analysis -- e.g., tolerance levels versus anticipated residues in the diet. It will be necessary for EPA to determine the appropriate situations for use of crop field trial, processing, and/or monitoring data, and the most appropriate percentile of residue for an estimation of potential dietary exposure.

(5) Data presentation. Since the TAS is a complex system, the SAP was asked to comment on the presentation of TAS data in a hypothetical case example, and provide guidance as to how the data presentation might be improved.

In addition to the specific recommendations I have mentioned, the FIFRA SAP made the following generic recommendations regarding the TAS issues presented by EPA: (1) A judgmental or weight-of-evidence step should be factored into the system, to account for the degree of scientific uncertainty that may be associated with quantifications of exposure and risk; (2) There is a danger of taking a "formula" or "protocol" approach to implementing the system, which could leave little or no flexibility for the regulator; for this reason, EPA needs to consider how "relevance, biological significance, and other issues" could be introduced into the process. EPA is now moving toward resolution of these policy issues, taking the recommendation of the FIFRA SAP into account.

TOLERANCE REASSESSMENT

In addition to generic policy issues inherent to the new TAS, EPA is now confronting a number of issues that have arisen in the context of tolerance reassessment for existing pesticides. The vast majority of Registration Standard reviews that EPA has completed on existing agricultural chemicals have identified substantial deficiencies in the data supporting previously established tolerances. The Agency has acted to rectify these deficiencies and is now beginning to receive from pesticide registrants the necessary data to enable us to complete tolerance reassessments on a number of existing food-use chemicals. Realistically, we know some of these tolerance reassessments will show problematic risks that may warrant regulatory action. As a regulatory option short of cancellation, it may be necessary to lower tolerances for some existing pesticides. Lower tolerances may require substantial changes in agricultural practices which in some instances suggests that certain crops may not be profitably grown in some areas of the country. In other instances, EPA may find that existing tolerances require revision to lower levels simply because up-to-date residue data may show that an established tolerance is unnecessarily higher than actual post-harvest residue levels.

There are several significant issue areas that EPA will be grappling with on a chemical-specific basis as we proceed with tolerance reassessment on specific agricultural chemicals:

TMRCs in Excess of an ADI

In conducting Registration Standard reviews, EPA has found the Theoretical Maximum Residue Contribution (TMRC) for some existing pesticides to be in excess of an ADI. In particular, this has happened in cases where (1) the ADI is "provisional" and therefore reflects a compensatory margin of safety (generally 1,000 rather than 100) due to deficiencies in the toxicology data base, or (2) the ADI has been changed as a result of a consensus action by EPA's Agency-wide ADI review committee.

Drinking Water Exposure

As part of EPA's comprehensive Pesticides in Ground Water Strategy, we will be considering the impact of pesticide residues in drinking water, as well as foodstuffs, on residue contribution estimates to the diet. This is a technically difficult area; however, it is an area that EPA must deal with in order to get a complete picture of exposure in comparison with ADI levels. In cases where pesticides do reach drinking water supplies, it is necessary to factor this exposure into tolerance decisions.

FIFRA/Delaney Integration

Two years ago, EPA commissioned the National Academy of Sciences to study the scientific and regulatory implications of the differing statutory standards set by FIFRA and FFDCA section 408 versus the Delaney clause of FFDCA section 409, in the overall context of both agricultural production and the public's dietary exposure to pesticide residues. FIFRA specifically sets a risk/benefit standard for pesticide decisionmaking. FFDCA section 408, which governs tolerances for pesticide residues in or on raw agricultural commodities allows EPA to make tolerance decisions in concert with risk/benefit decisions under FIFRA. However, the Delaney clause of FFDCA section 409 appears to set a zero-risk standard, prohibiting the establishment of tolerances for food additives -- including pesticides -- in processed commodities if the substance is found to induce cancer in animals, with certain limited exceptions.

The Academy's report arrives at an opportune time. As my testimony has outlined, we have been developing and evaluating key prerequisites for the last several years. This report and its recommendations are one of the key elements in concluding our redefinition of policy goals and implementing them in the reregistration of existing pesticides. Having read through the report, let me say that I find its overall recommendations to be sound and reasonable. However, the report deserves detailed study and discussion by the Agency as to the specifics of implementation. The Academy has recommended that pesticides should be regulated on the basis of a consistent standard, with the same yardstick applied to old and new chemicals, and to raw and processed foods.

Conceptually, I find these recommendations particularly sound; my only concern is the extent to which EPA will be able to implement these recommendations without confronting disabling legal obstacles through litigation.

The report correctly states that EPA has not yet made chemical-specific policy decisions where the Delaney clause may apply, retrospectively, to existing food additive tolerances for registered pesticides. As you know, however, we have been implementing a rigorous interpretation of the Delaney clause in section 409 with respect to new chemicals, and new food uses of existing chemicals. We have had instances where exceptions to the Delaney clause have clearly applied. These case-by-case decisions need to be evaluated in the broader context that is embodied in the NAS report.

For existing chemicals, the Delaney clause became problematic to EPA as we began to identify, through the reregistration process, a number of specific pesticide uses that highlight the difference between the statutory standards of FIFRA and section 409 of FFDCA. Two sorts of problems have arisen. First, new risk data in some instances have indicated that a pesticide with existing registrations and associated food additive tolerances induces cancer in test animals. Second, in other instances, new residue data have indicated the need for food additive tolerances for a pesticide known to induce cancer in animals. If the level of risk posed by such pesticides is significant, it is clear that regulatory action under both statutes is appropriate. However, when the pesticide meets the risk/benefit test of FIFRA, but not the Delaney standard, the proper course of action is much more difficult to chart. These are the kinds of cases where EPA has so far deferred making specific Delaney clause decisions.

Apart from making these specific policy calls, we have otherwise proceeded with the necessary groundwork for tolerance reassessment. Through our Data Call-In and Registration Standards program, we have been calling in the necessary data to support tolerance reassessments on individual chemicals, and we are now receiving the data necessary to make tolerance reassessment decisions on a number of existing chemicals. For the past few years, we have been working together with FDA, and more recently with USDA, to improve analytical methods for tolerance enforcement for existing chemicals, where such methods have been identified to be impractical in the field. As I have previously described, we have developed the newly computerized Tolerance Assessment System for the analysis of dietary risks, and we are urging pesticide registrants and other parties to provide detailed pesticide residue and usage data where such data may be necessary to support existing tolerances.

EPA has begun the process of developing regulations governing the setting, amendment, and repeal of food additive tolerances under section 409 of FFDCA as well as raw agricultural commodity tolerances of FFDCA section 408. These regulations will focus on establishing formal procedures and also defining specific criteria concerning the circumstances under which existing food additive tolerances for pesticides may be revoked due to oncogenic considerations. The Academy's report will be of assistance to us in defining these circumstances.

With the groundwork laid for tolerance reassessment of existing chemicals, the Academy's report gives EPA the wherewithal to frame a coherent policy applicable to both old and new agricultural chemicals, and to proceed with the reassessment of tolerances for existing chemicals in concert with reregistration under FIFRA. The Academy's thoughtful, balanced recommendations will serve us well as we complete the construction of policies governing food tolerances as they relate to agricultural pesticide use in this country.

These comments conclude my prepared statement. My staff and I are prepared to provide any assistance you may need in considering the issues I have discussed today.

Charts 1-5 follow:

CHART 1

RESIDUE LEVELS IN TREATED POTATOES SAMPLED DURING STORAGE

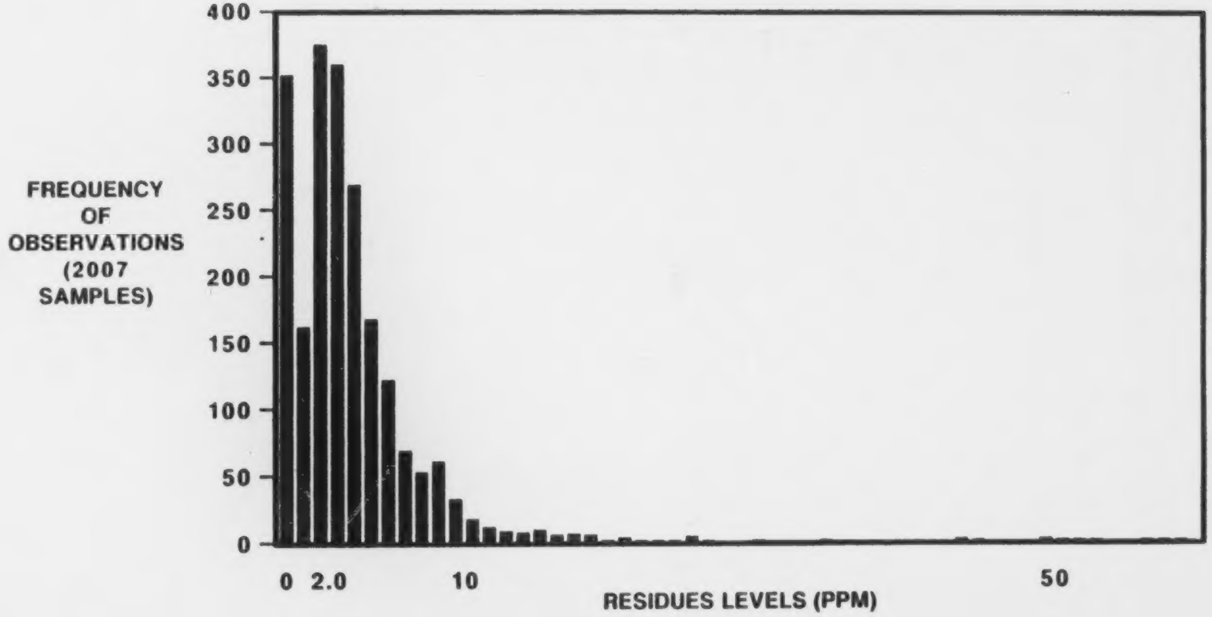


CHART 1: FIRST OVERLAY

RESIDUE LEVELS IN TREATED POTATOES SAMPLED DURING STORAGE

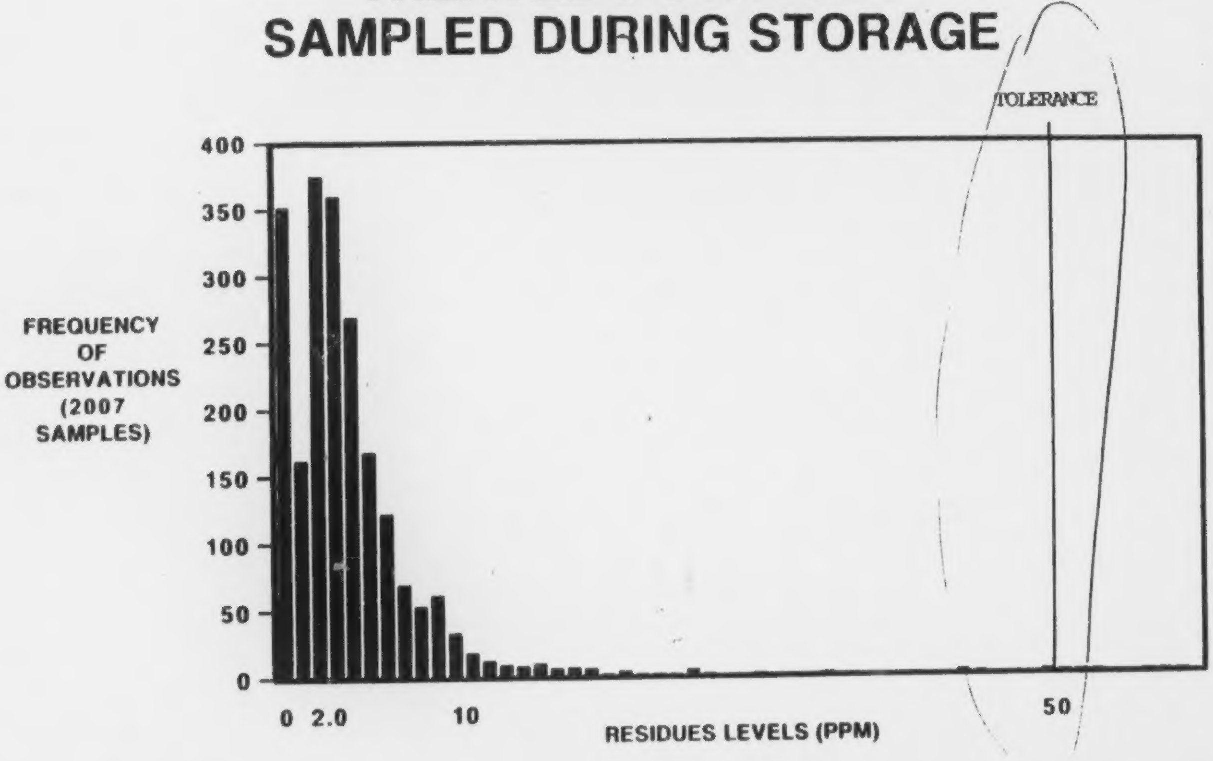


CHART 1: SECOND OVERLAY

RESIDUE LEVELS IN TREATED POTATOES SAMPLED DURING STORAGE

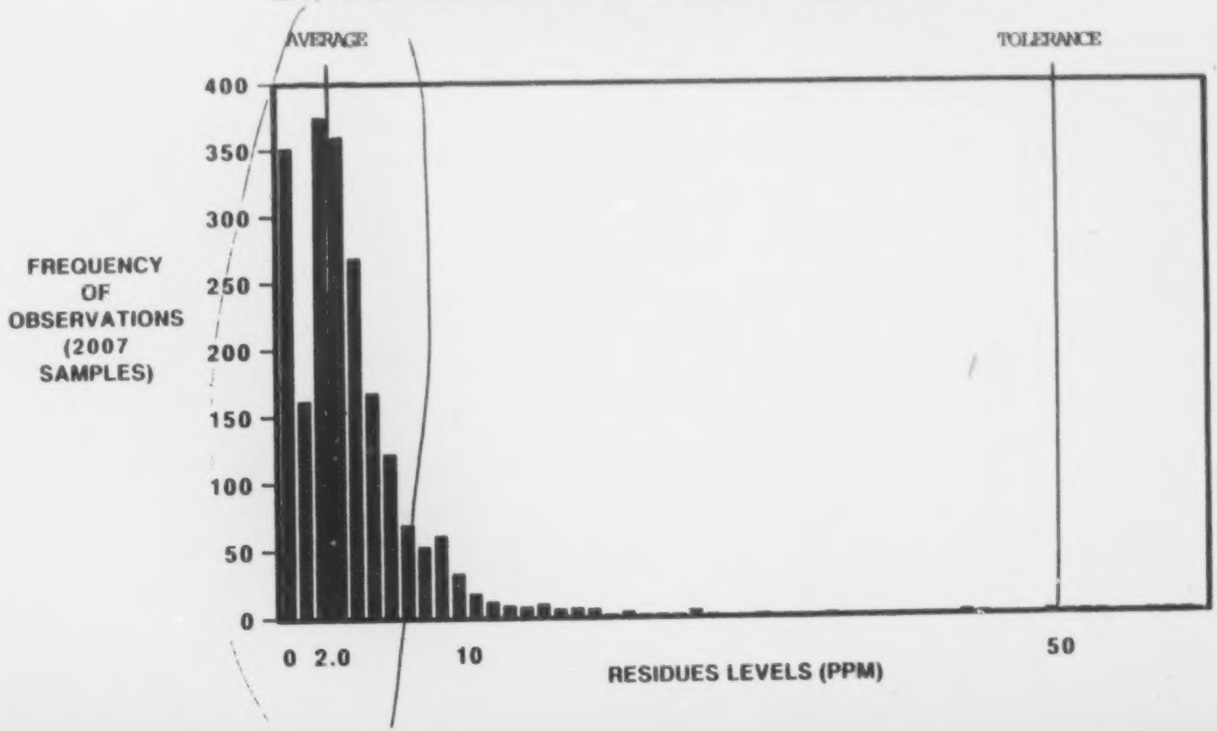


CHART 1: THIRD OVERLAY

RESIDUE LEVELS IN TREATED POTATOES SAMPLED DURING STORAGE

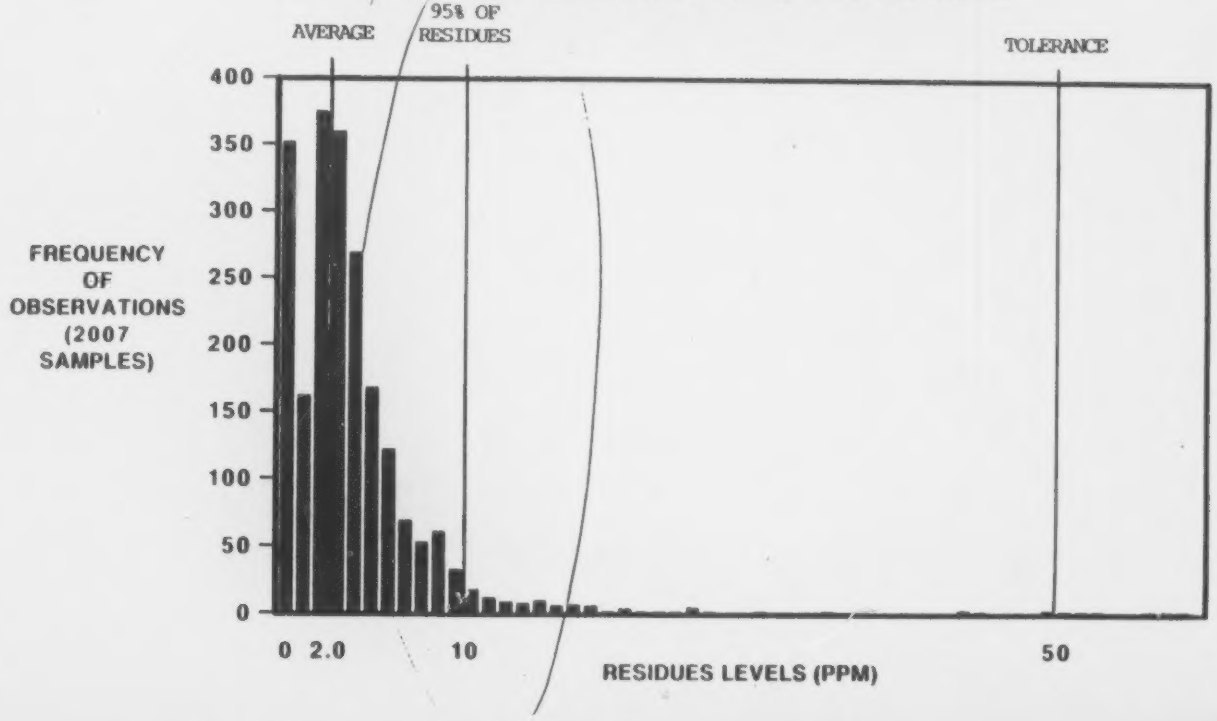


CHART 2

CHANGES IN RESIDUES DURING PROCESSING AND STORAGE FOR THREE HYPOTHETICAL CHEMICALS

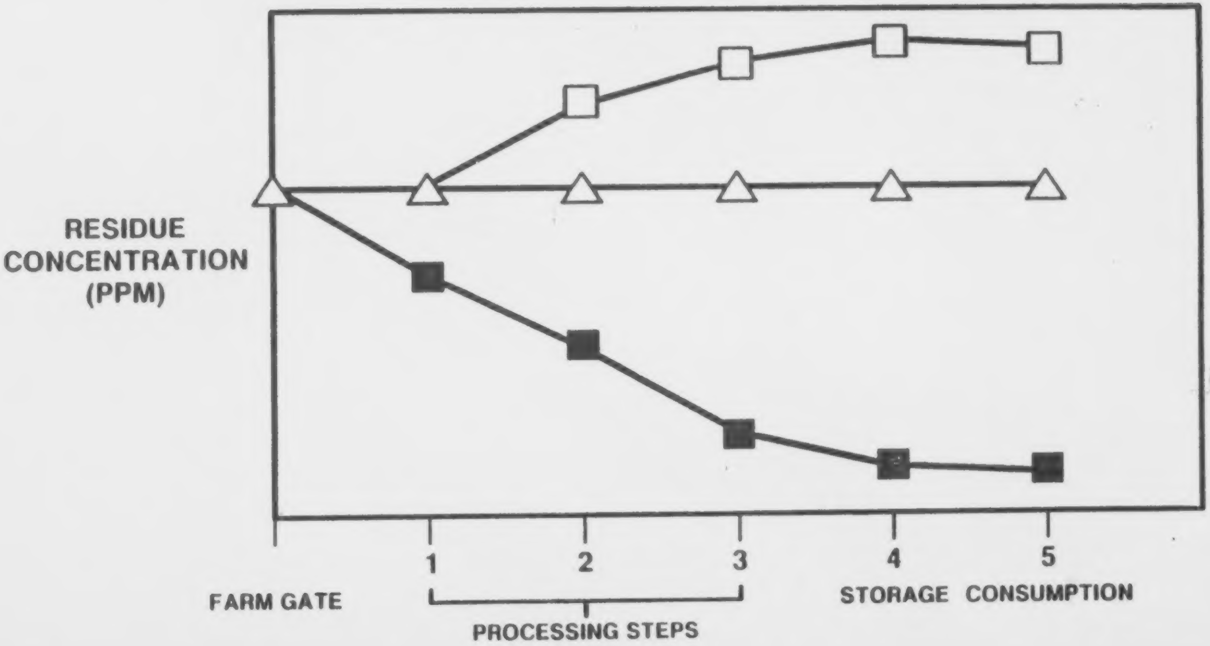
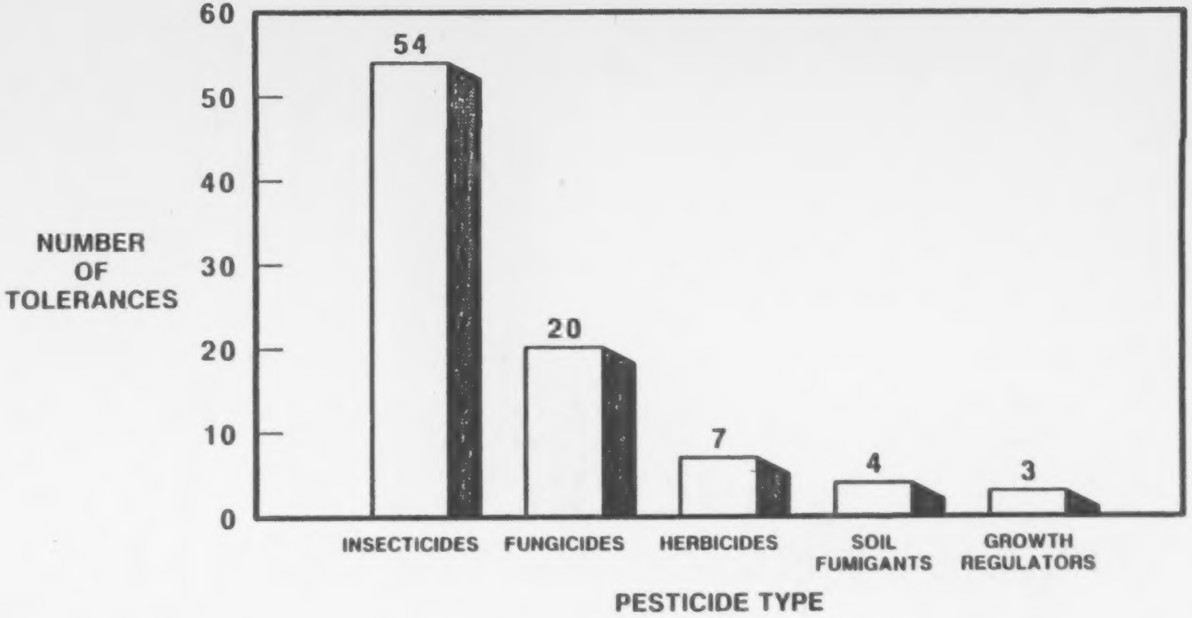


CHART 3

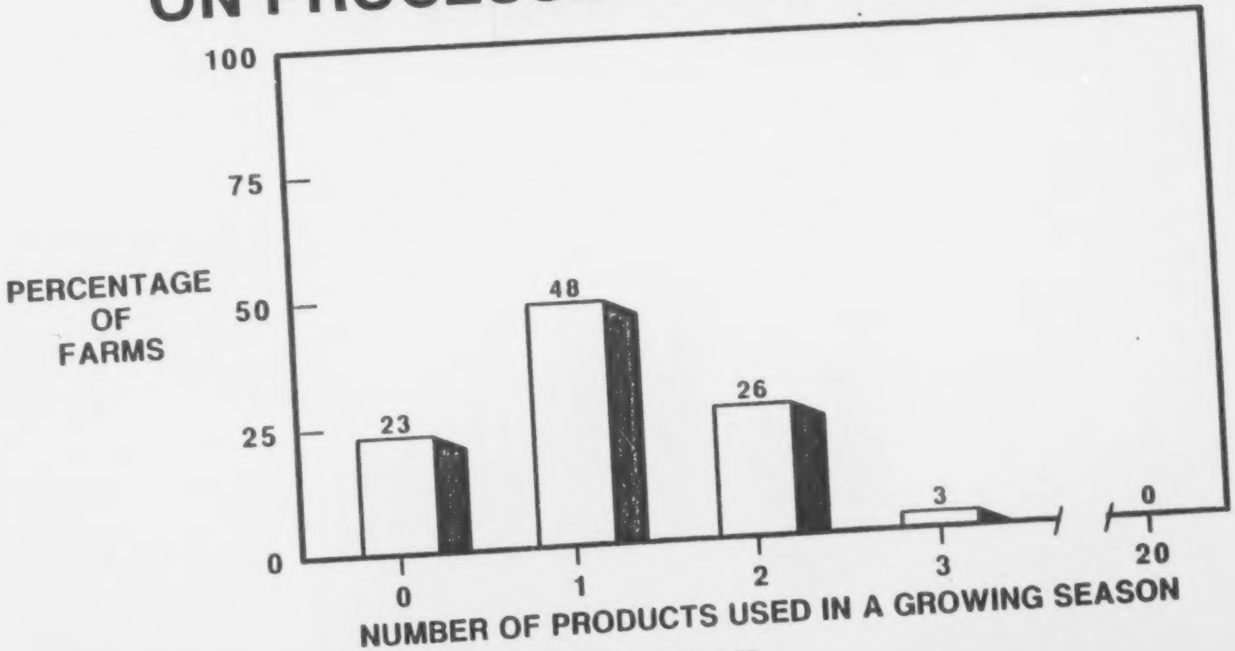
TOLERANCES FOR TOMATOES BY PESTICIDE TYPE



SOURCE: CODE OF FEDERAL REGULATIONS (40.180)

CHART 4

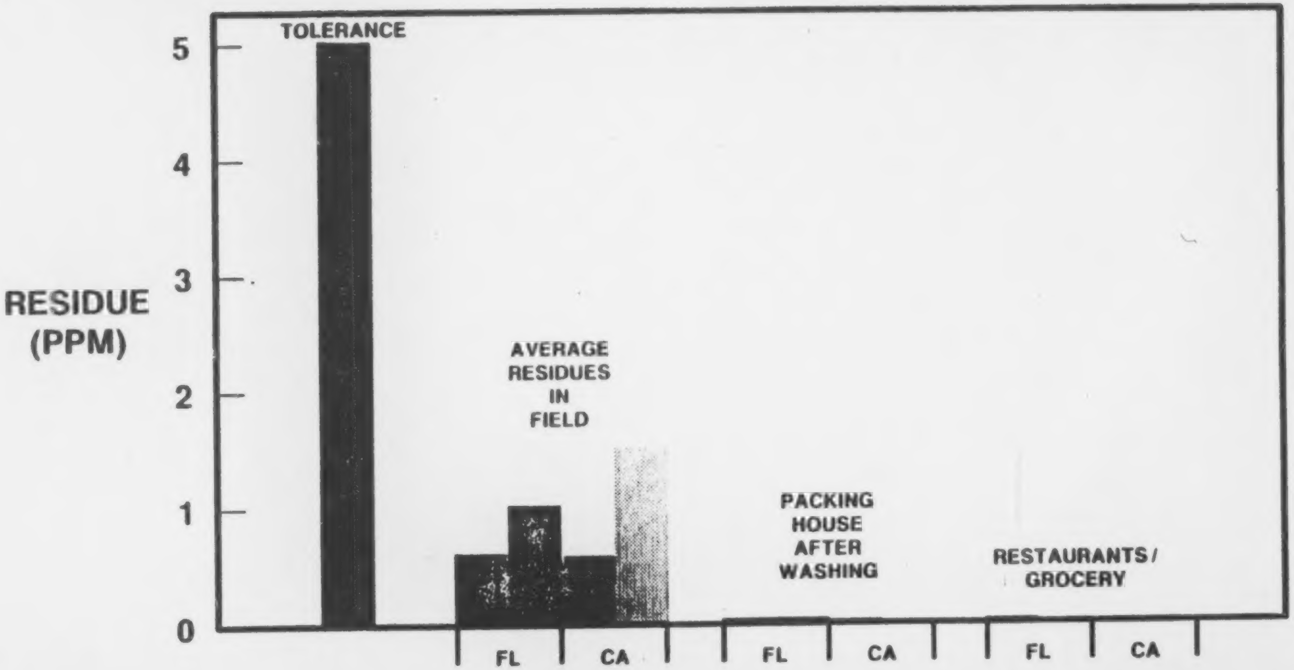
PERCENTAGE OF FARMS USING FUNGICIDES ON PROCESSING TOMATOES



SOURCE: CALIFORNIA TOMATO GROWERS ASSOCIATION, INC. MAY 1987

CHART 5

TOLERANCE AND ACTUAL RESIDUES MEASURED ON FRESH TOMATOES



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 24 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Chairman Patrick Leahy
Committee on Agriculture,
Nutrition and Forestry
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your letter of May 21, 1987, transmitting follow-up questions to the May 20 hearing on pesticide residues in food.

I have enclosed responses to each of the questions. Should you or your staff have any additional questions, or if we may be of assistance in any other way, please do not hesitate to contact me.

Sincerely yours,

John A. Moore
Assistant Administrator
for Pesticides
and Toxic Substances

Enclosures

SENATOR LEAHY'S FOLLOW-UP QUESTIONS TO
JOHN A. MOORE, ASSISTANT ADMINISTRATOR
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Question 1:

The National Food Processors testified that the concentration of residues in processed food will seldom if ever exceed the tolerance set for raw foods, and that, as a result, the Delaney clause shouldn't apply. Is that true? What is your response to that argument?

Answer:

Another way of thinking of this question is, "Since actual residues of pesticides on raw agricultural commodities (RACs) are, on average, somewhat lower than the 408 tolerance level, and actual residues on processed foods seldom exceed the 408 tolerance, why set a 409 tolerance for processed food?"

The answer to this question is rather complex and depends on a number of factors. In accordance with the language of section 408 of FFDCA, 408 tolerances are set to reasonably reflect the highest levels of residue anticipated with legal use of the pesticide. They are enforcement tools set at a maximum allowable level, but as low as possible without resulting in seizure of properly treated crops.

The actual residues on the RAC will depend on such variables as climatic conditions, soil type, and application rates or timing. Thus, actual residues for the same RAC may vary from year to year and from farm to farm. While a large proportion of the total crop will have actual residues well below the 408 tolerance, some small percentage of the crop will have residues at or near the tolerance level. Those high residue commodities, when processed, would almost certainly have residues exceeding the 408 tolerance level if any significant concentration occurs during processing.

In general, a 409 tolerance is required if pesticide residues concentrate by 10 percent (1.1x) or more. In some cases, we see evidence of pesticide concentration in excess of 100x. The concentration factor for the majority of cases for which 409 tolerances are required ranges from 2x to 100x. If the concentration factor is 2x, the concentrated residue will rarely (probably less than 1 percent of the time) exceed the 408 tolerance. If the concentration factor is 100x, it nearly always will.

If the Agency eliminated the 409 tolerance and simply prohibited residues in processed foods in excess of the 408 tolerance, it would either result in a 408 tolerance which was acceptable for the RAC but too low for some processed foods, or a 408 tolerance which was artificially high for the RAC and accommodated processed foods. The Agency does not have sufficient data about actual residues under various conditions to estimate how frequently the processed food residues would exceed the 408 tolerance. However, in some cases, only 1 percent of processed foods from a crop would have residues exceeding the tolerance, in others perhaps 10 percent would be over-tolerance and thus subject to seizure. It would be difficult to justify the seizure of processed foods which were properly treated, because the Agency relied solely on the 408 tolerance which was set at the proper, lower level for the RAC. It would be equally difficult to justify allowing the RAC to be exposed to greater than necessary levels of pesticide and would pose an unnecessary risk to public health.

It is important to realize that food processors often combine raw produce from several sources. This is probably the chief reason residues on processed foods seldom in fact exceed the 408 tolerance. For example, tomato paste "A" contains tomatoes from many farms, only 25% of which were treated with herbicide "H". Tomato paste "B" is made up of tomatoes, all of which were treated with "H". All else being equal, residues of "H" in "B" will be 4 times those in "A". The residue of "H" in tomato paste "A" is not likely to exceed the 408 tolerance; however, residues in "B" are likely to exceed the 408 tolerance. The Agency must base its assumptions on the case where all of the raw produce has been treated because in some cases that may be true.

Question 2:

The NAS Report says on page 28 that EPA prohibits tolerances on processed food if residues concentrate at all, not if residues are above the raw food tolerance. Is that true? If so, it seems as though the Agency is making its own job more difficult for the Food, Drug and Cosmetic Act clearly allows such an exception to the Delaney clause.

Answer:

EPA requires a 409 tolerance for a pesticide which is to be used on a commodity which may be processed where that processing has been shown to significantly concentrate pesticide residues. As discussed in my previous answer, we consider a concentration of 10% (1.1x) or more to be significant. According to the Delaney Clause, with certain limited exceptions, if a pesticide is demonstrated to be carcinogenic to people or animals, a 409 tolearnce may not be established.

Since the FFDCA requires that 408 tolerances reasonably reflect the amount of residues likely to result when the pesticide is used in the manner proposed, some percentage of the treated RACs will contain residues at a level near the tolerance. When there is a significant concentration of residues during processing of those RACs which bear residues at or near the 408 tolerance level, residues in the processed food will be above the 408 tolerance.

If RACs containing residues near the tolerance level are processed and residues concentrate, the residue levels in the processed commodities will exceed the RAC tolerance. It is also true that residue levels in RACs can be well below the RAC tolerance; then the RAC could be processed and the residues will still not be above the RAC tolerance. EPA sets the food additive tolerance high enough to cover the worst case because of the severe economic consequences for farmers and food processors that would occur if even a small percentage of a crop has to be seized and destroyed because of over-tolerance residues.

Question 3:

The Report indicates that there are substitutes for most herbicides and insecticides on the list. Why then doesn't the Agency move to cancel the oncogenic pesticides?

Answer:

First, it should be emphasized that FIFRA is a risk/benefit statute; the risks of any use must be weighed against its benefits. If the benefits exceed the risks, a pesticide can be registered or maintain its registration, even if it has oncogenic potential. The Report is correct in that there are substitutes for most of the herbicides and insecticides on the list. Some of the pesticides on the list are currently under Special Review, and regulatory decisions could lead to their cancellation (alachlor, chlordimeform). For pesticides which are oncogenic, the Agency does a risk assessment in accordance with our carcinogenic risk assessment guidelines. If the estimated risks associated with the pesticide's use are deemed unacceptable in light of its benefits, then regulatory action is initiated against the pesticide.

However, it would be premature for the Agency to seek to cancel all the oncogenic pesticides.

° Not all of the substitutes have been adequately tested for oncogenicity. The Agency is requiring data either through Data Call-Ins or through Registration Standards to fill data gaps for these substitutes. We can expect that some of these will be oncogenic and likely present similar or even greater risks than those on the list.

- It is likely that the oncogenic risks for some of the pesticides on the NAS list are less than the non-oncogenic risks of some substitutes.

- A number of problems may occur when a limited number of pesticides are available for use on a crop--for example,

  1) Variations in environmental conditions in different parts of the country may create a need for a variety of pesticides. For example, where soils are dry, one type of fungicide might work well, but in an area that tends to be wet, that same fungicide might not work well, and one which works better could be used at a lower application rate.

  2) The development of pest resistance to one or more pesticides may make them useless against that pest. One way of avoiding or delaying the onset of pest resistance, is to use two or more chemicals in combination (allowing less of any one chemical to be used) or periodically to switch to a different chemical.

  3) The effectiveness of any given pesticide is often limited to specific strains of the pest.

In such cases as those listed above, the benefits of having multiple pesticides available for a particular use may exceed the risks attributable to some of those chemicals. It is not reasonable or prudent to cancel all oncogenic pesticides automatically without consideration of all the risks and benefits. The Agency should pursue analysis and evaluation whenever an oncogenicity concern is raised to determine the proper course of action, taking into account the risks (oncogenicity and other risks) and benefits of the pesticide in question and its substitutes. In fact, this approach is mandated by FIFRA.

Question 4:

The Report also states on page 8 that there are certain fungicides for which there are no non-oncogenic substitutes. Is this correct? What about the fungicide metalaxyl? Is it oncogenic?

Answer:

EPA did have some concerns over the oncogenic potential of the fungicide metalaxyl. However, it was determined to be non-oncogenic after data were reviewed by both the Agency's Cancer Assessment Group and the Hazard Evaluation Division of the Office of Pesticide Programs.

The Report is correct when it states that there are certain fungicides for which there are no non-oncogenic substitutes. In the case of benomyl, for example, alternatives are the EBDCs, captan, and captafol (all of which have oncogenic potential). Fosetyl Al (Aliette), which has demonstrated weak, but positive oncogenic effects, is also a substitute for benomyl in some cases. However, Aliette is not a broad spectrum fungicide, and the range of pests it controls is much narrower than benomyl. Metalaxyl can be used for some of the same purposes as benomyl; however, because it characteristically develops pest resistance very rapidly, metalaxyl is only registered for foliar use in combination with other fungicides (all oncogenic). By combining metalaxyl with another fungicide, the application rate of each is reduced and the opportunity for resistance build-up is also reduced, thus delaying the on-set of pest resistance.

Question 5:

Does current law give you the flexibility to register a weak oncogen for a particular use, if you are simultaneously cancelling a much more potent one with the same use? Do you think that it would be a sensible policy decision?

Answer:

With regard to FIFRA and FFDCA section 408, the answer to this question is definitely yes. FIFRA specifically sets a risk/benefit standard for pesticide registration decisions, and FFDCA section 408, which governs pesticide tolerances for raw agricultural commodities, implies a risk/benefit standard by requiring that tolerance decisions take into account the need for "an adequate wholesome, and economical food supply." Thus EPA does register and approve FFDCA §408 tolerances for weak carcinogens that have offsetting benefits.

We may register such a weak carcinogen whether or not we are simultaneously cancelling a more hazardous chemical with the same use. In fact, the Agency rarely has the opportunity to make such decisions simultaneously. This question actually assumes greater coordination between the development of new chemicals and the evaluation of old chemicals than usually occurs, given the number of different factors affecting these two processes. But in either case we believe this is a sensible policy decision and one that is in fact mandated by FIFRA and FFDCA §408.

Under section 409 of FFDCA, the answer to this question is less clear-cut. A literal application of the Delaney clause of FFDCA section 409 would preclude approval of a weak carcinogen if it is proposed for a use that requires one or more food additive tolerances. However, EPA favors the application of a "negligible risk" approach to pesticide decision-making across all pesticide uses, as recomended by the NAS. Based on a "negligible risk" interpretation of FFDCA section 409, the answer to the question would be yes, even if the new pesticide use required 409 tolerances.

A negligible risk standard for administering section 409 of FFDCA is analogous in some respects to the so-called "de minimis doctrine", which the Food and Drug Administration has recently applied in its decision to approve two color additives for non-ingested uses. Initially, these additives were thought to be oncogens since they were found to cause cancer in the laboratory animals under certain conditions. However, by using the Agency's new quantitative risk assessment techniques, it was determined that, at the levels to which humans are actually exposed, the additives pose such a small risk of cancer in man or animals that the health risk is essentialy non-existent. However, FDA's de minimis interpretation has been challenged, and a court decision is pending at this time.

Question 6:

Do you favor the use of a grouping of pesticides over regulating one at a time? Can you do it under current law?

Answer:

Yes, the Agency does have the authority under current law to regulate groups of pesticides instead of regulating one pesticide at a time. The Agency supports such an approach; in fact, we have taken this approach with the wood preservatives and grain fumigants and for certain fungicides and crop patterns. The NAS Report has recommended that EPA employ the use-cluster approach to pesticide regulation as often as possible. EPA believes this is generally a sound recommendation. However, we must keep in mind that, by grouping pesticides, reaching a decision about a pesticide likely will take longer, because the decision will be made after reviewing data about many pesticides. On the other hand, decisions on all pesticides registered for a given crop may be better because they would be based on a comprehensive review.

Question 7:

Must tolerances be set for inert ingredients of pesticides? If so, how--by what standard--are they set? If not, when will they be set?

Answer:

Any pesticide chemical used on food must have a tolerance or an exemption from the need for a tolerance. This includes both active and inert ingredients. To date, EPA has not set tolerances for inert ingredients, except for those chemicals which are used as both active and inert ingredients. Although we have generally granted broad exemptions from the requirement of a tolerance for inert ingredients, we have occasionally granted these exemptions with very specific conditions. These conditions might limit the amount (percentage of the formulation) included in the pesticide; allow use only for certain use patterns; or allow use only in combination with certain pesticide active ingredients. Under the new inert ingredients policy (52 FR 13305), significantly fewer broad exemptions from the requirements of a tolerance will be granted. We also intend to establish tolerances for inert ingredients when the toxicity data that are now required for new inert ingredients indicate a potential hazard. These tolerances will be set by the same standards as those we set for active ingredients.

Question 8:

You testified that the Report overstated the risk of exposure by assuming residues of pesticides are at tolerance. What about exposure through other means, such as ground water, to the same pesticide? You told the Committee last month that EPA does not take exposure into account in setting standards for water and vice versa. Also, what about multiple pesticides in the same food? Do we know what kinds of cumulative or synergistic effects this exposure may have?

Answer:

We are concerned about human intake of pesticides via routes other than food, in particular water. Historically, the Agency has based its decisions on tolerances only on dietary exposure from foods treated with pesticides. More recently the Office of Pesticide Programs (OPP) and the Office of Drinking Water (ODW) have begun focusing on drinking water as a potential source of pesticide residues in the diet. The Agency has recently made significant progress in its efforts to integrate activities of OPP and ODW with respect to pesticides in ground water. All Health Advisories for pesticides in drinking water are now developed jointly by ODW and OPP, using the same data base and the same reference dose.

As a part of EPA's comprehensive Agricultural Chemicals in Groundwater Strategy, we will be considering the impact of pesticide residues in drinking water, as well as in food, on estimates of residue contribution to the diet. This is a difficult area; however, it is an area that EPA must deal with in order to get a complete picture of exposure in comparison to Acceptable Daily Intake levels. In cases where pesticides do reach drinking water supplies, it is necessary to factor this exposure into tolerance decisions.

Exposure through drinking water as a result of the presence of aldicarb in groundwater was considered in the tolerance assessment in our special review of aldicarb. This was a case in which the data were available and it was clear that drinking water is a potential route of exposure. The question which the Agency must now address is, "Under what circumstances should we use combined exposures to best protect public health?" This is one of a number of dietary exposure questions on which we are beginning to focus.

In terms of multiple pesticide residues on the same food, it should be made clear that the residue level of every pesticide must be within a tolerance (or action level) or it is an illegal residue. But, the Agency is only at the early stages of developing knowledge on the synergistic or antagonistic effects of multiple residues. Generally, toxicologists have very little evidence of these effects, thereby making the regulators' jobs extremely complicated. In addition, research indicates that synergistic and/or additive effects are normally only seen at very high dosages. Thus, of necessity, we have chosen to treat active ingredients individually.

Question 9:

Do you believe that EPA should cancel oncogenic pesticides if there is a non-oncogenic alternative? Can EPA do this under current law? If so, then why are the chemicals on the NAS list still on the market?

Answer:

The Agency should seek to cancel any pesticide when the risks, oncogenic or non-oncogenic, exceed benefits. However, caution should be exercised before considering cancellation of an oncogenic pesticide just because there is a non-oncogenic alternative. There are a variety of characteristics which contribute to risk, including teratogenic effects, reproductive impairment, cholinesterase inhibition, and other chronic effects. In addition, in any risk/benefit analysis, environmental impacts must also be considered. Total risks associated with the non-oncogenic alternative could be greater than risks associated with the oncogenic pesticide.

There may also be important benefits associated with the continued use of an oncogenic pesticide, for example, pest resistance is a problem, especially with the fungicides and insecticides. Grower reliance on a single insecticide or fungicide (the non-oncogenic alternative) frequently results in rapid development of pest resistance. For this reason, automatic cancellation, just because a non-oncogenic alternative exists, would be unwise.

Under current law, EPA clearly can move to cancel any pesticide when risks are greater than benefits. It is unlikely the Agency could or would cancel all the chemicals on the NAS list. To cancel all oncogenic pesticides, simply because they are oncogenic and without regard to other risks or benefits, would require a change in the law and, in the final analysis, may not be the best way to protect the public health.

Question 10:

What about the remaining 25 pesticides on your list of 53? Is there sufficient data available on them to analyze their carcinogenic risk? How serious is the data gap problem for oncogens?

Answer:

EPA does not have the data necessary to analyze each of the remaining 25 pesticides and this is clearly a problem. Yet, the Agency has been actively addressing the need for data for a number of years, and the magnitude of the problem is being reduced. The data needed to complete evaluation of the 25 chemicals are now or will be required by data call-in or registration standard action. Once all data are received, each of the chemicals will undergo appropriate evaluation and tolerance reassessment.

Question 11:

Is the real issue that these pesticides are oncogens and that they are old pesticides which are tough to get rid of? Isn't this evidence that FIFRA isn't working rather than a major problem with the Delaney clause.

Answer:

There are really two fundamental problems. First, there is indeed a statutory conflict between the standard EPA must use for decision making under FIFRA and FFDCA Section 408 and the standard used under FFDCA section 409. Under FIFRA and section 408, the standard is a risk/benefit one. The Agency is able to permit the use of oncogenic pesticides if the benefits outweigh the risks. The standard for decision making is clear.

However, FFDCA Section 409 sets an ostensible zero-risk standard for decision making on pesticides that are animal carcinogens. Use of a "negligible risk" standard for administering section 409, as recommended by the NAS Report, would go a long way toward reconciling these differing statutory standards. The problem is how to resolve the statutory conflict.

Second, it sometimes is in fact difficult to get old pesticides off the market. But this is a problem more related to the cumbersome regulatory processes of FIFRA. However, it can and is being done.

Question 12:

Please provide the Committee with the regulatory status of the 28 pesticides covered in the NAS report.

CHEMICAL	REGULATORY STATUS
Linuron	Issued Registration Standard, Under Special Review
Zineb	Issued Data Call-In Under Special Review
Captafol	Issued Registration Standard, Voluntary Cancellation
Captan	Under Special Review, Issued Registration Standard

Maneb	Issued Data Call-In Under Special Review
Permethrin	Weight of the Evidence Review, Established Tolerances and Issued Registrations
Mancozeb	Issued Registration Standard Under Special Review
Folpet	Registration Standard Issued
Chlordimeform	Under Special Review; Issued Registration Standard
Chlorothalonil	Issued Registration Standard, Oncogenic Potential Under Review
Metiram	Issued Data Call-In
Benomyl	Issued Registration Standard (Special Review completed)
Orthophenylphenol	Issued Data Call-In
Acephate	Issued draft Registration Standard
Alachlor	Under Special Review; Registration Standard Issued
Parathion	Under Special Review; Registration Standard Issued
Metolachlor	Issued Registration Standard and Draft Final Registration Standard and Tolerance Assessment (FRSTR)

CHEMICAL	REGULATORY STATUS
Oryzalin	Issued Registration Standard
Oxadiazon	No Food Uses Registered in U.S.
Pronamide	Issued Registration Standard
Cypermethrin	Registered Based On Quantitative Risk Assessment
Ethalfluralin	Recently Established New Tolerances, Complete Data Base
Diclofop-Methyl	Registered Based On Quantitative Risk Assessment
Cyromazine	Issued Registrations, Minimal Oncogenic Risk
Terbutryn	Issued Registration Standard
Glyphosate	Issued Registration Standard Not Regulated as Oncogen
Fosetyl-Al	Issued Registration Standard and draft FRSTR
Azinphos-Methyl	Issued Registration Standard

The CHAIRMAN. Are we really getting to the point where we can? According to the Academy's testimony, 1.5 million Americans could get cancer because of just 28 pesticides.

One group, EBDC's, could result in 240,000 extra cancer cases alone. They say we could eliminate as much as 90 percent of the estimated cancer risk posed by dealing effectively and immediately with just 12.

We understand that the EPA has not been supplied with enough data in some of these areas. There have been such cutbacks in funding that EPA cannot remove some of these.

Now as I have said several times in this hearing, we do not want to exaggerate any of the risks, but I do not want to gloss over them either.

Of the top cancer risk pesticides, 4 of 12 are EBDC's. According to their report, 1,000 times the risk that they find acceptable. EBDC's create a risk 1,000 times higher.

They went through a review, but the EPA, in 1982, gave them a clean bill of health, did they not?

Dr. MOORE. Senator, based on what the Agency did in 1982, it took a look at that class of chemicals, concluded it did not have all of the data that was needed, and recommended some, what I would consider to be modest, changes in the way that the material is applied. It did not wish to suggest that indeed we were done with the review of those materials.

The CHAIRMAN. Well then, what happened after 1982?

Dr. MOORE. Well, a lot happened after 1982. Among other things, there was a litigation between us and a group on a variety of chemicals of which EBDC's are included. Indeed, this was settled out of court with a commitment on the part of the Agency to relook at the EBDC's, with some other materials, as a function of that settlement. We are in the process of doing just that.

The CHAIRMAN. Does that mean the Agency did it only because they were sued?

Dr. MOORE. Well, one cannot answer that in retrospect. It is quite clear, that as a condition of settlement of the suit, we did agree to go back and revisit that as well as several other chemicals.

I might also point out that we probably would have got to those anyway, as we would do to all older registered pesticides, as part of our review process when we have full data.

We clearly, as a part of this settlement, got into a process of identifying when and how we would go about reviewing those EBDC's.

The CHAIRMAN. But 5 years are lost?

Dr. MOORE. Well, it is 1987 right now. I think what was identified in part of the negotiation of that consent settlement was also setting the timing of some of those reevaluations consistent with the receipt of actual data. Doing that would allow us all to make decisions based on fact as opposed to having to make them by analogy.

The CHAIRMAN. But were they given a clean bill of health in 1982 under Mr. Todhunter?

Dr. MOORE. I am reluctant, Senator, to say whether or not it was a clean bill of health, or not, because I did not review that in preparation of today's testimony.

Clearly, they concluded that evaluation, suggesting only modest changes, and I think, based on what we know about EBDC's today, that it would be sufficient to say that we should go back and revisit them.

I think we should, particularly because of a common metabolite that is associated with those materials, that is a problematic concern, the ethylene thiourea.

The CHAIRMAN. Do you favor the use of a grouping of pesticides over regulating one at a time?

Dr. MOORE. I think there is no question that the recommendation of the Academy, that one look at a crop pattern like fungicides on tomatoes, or a number of other crops, is a preferred way to go. In fact I would suggest that we have done that with some of these fungicides and these crop patterns. Captan is another one of these fungicides that is identified as one of these chemicals that may be problematic. We have that chemical in special review.

We made a conscious decision a couple of years ago to delay our final decision, on the assumption that indeed, when we got actual residue data in, we would be in a better position to make the correct choice, presuming that the data would indicate that real residues would be one or two, or even more orders of magnitude lower than those theoretical calculations. In the final analysis, you might find that these theoretical risks have dropped sufficiently to be below the negligible risk standard that the Academy suggests.

The CHAIRMAN. Can you group pesticides that we are regulating one at a time under the current law?

Dr. MOORE. We can group or cluster our approach. I think sometimes what clearly has to be accepted in a grouping approach is in reaching the ultimate decision it is going to take longer. The reason for that is, obviously, you are trying to treat with more data on all pesticides at one time, than you would be by just looking at one pesticide on one particular crop.

We traditionally have looked at a given pesticide against all uses on all crops. I think what the Academy is suggesting, that there may be a preferred management approach in some instances, to look at the crop and then look at all pesticides that are used on that crop. I think it has merit, particularly when we get into a circumstance such as they characterize the fungicides to be.

The CHAIRMAN. Let me go back to EBDC again. The actions, or inactions as some might call them, of 1982, prompted the law suit. When does EPA intend to have regulations on EBDC's? What is your time schedule today?

Dr. MOORE. Senator, we completed the registration standard on two of those EBDC's, either late last year, or early this year.

Another one is proving to be problematic because we cannot get somebody to commit to do it. I am in the process, now, of maybe looking at it from a different perspective since these are fungicides which have a common chemical product, that really is the root of the concern. It may be that, we should just focus on that chemical, calculate the concern that we have with that as an oncogen, and then back-calculate from that level to all of the other fungicides, to find out whether or not one can continue to use those materials with the resulting residues low enough so as not to cause a problem with this metabolite.

This would then do four at once as opposed to one after the other.

The CHAIRMAN. Could you register a weak oncogenic chemical for the same time you are canceling a more potent one with the same use?

Dr. MOORE. Yes.

The CHAIRMAN. Does the law allow you to do that?

Dr. MOORE. The law clearly allows us, under section 408, to consider the registration of the chemical. It may be a weak oncogen, and, in fact, we do register such products when we estimate that the residues associated with that product basically get down into that level of minimal risk.

It becomes much more problematic, if, indeed, the use of that material on a particular product is involved in processing of foods, and you then have to consider setting a tolerance under the Delaney requirements of 409.

The CHAIRMAN. Will you be finished with reviewing all of the EBDC's by 1989? 1990?

Dr. MOORE. If we could take the approach that I have said we are looking at right now. If that proved to be an effective means of going about it, I think we basically could conclude where we need to be with that class of chemicals, in that timeframe.

The CHAIRMAN. Thank you.

Senator Pryor.

Senator PRYOR. No questions, Mr. Chairman.

The CHAIRMAN. Not even with the tomato charts down there?

Senator PRYOR. Well, I wanted to examine this a little more closely, and I've seen enough.

But I might just say that I'm a little bit concerned about some of the testimony from EPA today. I don't in any way, Mr. Chairman, want to make light of the findings nor of some problems that I think we've got in this whole area of pesticides and insecticides and fungicides. We've got some problems, and I don't think we can sweep them under the rug.

I just want to have them all in perspective, and that's my purpose.

That's all I have, Mr. Chairman.

Dr. MOORE. Senator Pryor, if I could, I might comment that I agree that there are some issues that are very difficult and vexing for the Agency, and it was that perception that led us in the beginning to ask the Academy to develop the report that we are discussing here today.

I think there is great merit in many of the recommendations of the report. I do think that some theoretical calculations that we focused on this morning do run the risk of being taken out of the perspective, out of perspective by some individuals.

That data I have shown give examples as to how those theoretical calculations don't match with real ones.

On the other hand, there are other uses and other crop patterns with some of these materials where it does not dissipate necessarily as a function of leaving the field and heading to the table and, indeed, you may have problems that need to be addressed.

The CHAIRMAN. Thank you, sir.

Senator Wilson.

Senator WILSON. Mr. Moore, your Agency having commissioned the report, and now in your testimony this morning having been critical of at least the presentation in somewhat the same fashion that Senator Daschle was critical, that it tends to deal with hypotheticals rather than the real world as you find it, let me just ask you a bottom line question.

In the judgment of EPA, how safe is the food supply of the American people, and are there things that need to be done by way of changes in the law to make it safer?

Dr. MOORE. Senator, I think one should not be worried about what they are consuming or purchasing at the supermarket and therefore consuming today or tomorrow or whatever, as a function of what's in this report.

I think the food supply is wholesome. I think it's safe. At the same time, can our approach to looking at pesticide residues and the uses of pesticides in agriculture, can it be improved? I think the answer to that is also yes.

I think the challenge of EPA is to take some recommendations, such as in this report, and try to improve upon the process. But I don't want to suggest that the process that we have in place right now is broken to such a degree that people need to get into heroic considerations on radical changes in their eating patterns or food consumption.

Senator WILSON. Have you had sufficient opportunity to digest this report and its recommendations so that you are able to say that the changes that you think are necessary require additional personnel or additional resources to your Agency in order to be performed in a timely fashion?

Dr. MOORE. Senator, as I testified before, and continue to state, the definition of timely is somewhat in the eyes of the beholder.

Clearly, to get through this reregistration of all pesticides, which is really what this report is heavily focused on, is a labor-intensive effort, and is amenable to more resources speeding up the rate of the process. And to the degree that one wants to see this process brought to conclusion at a rate faster than our current resources are carrying them, one might want to invest the resource.

If one is satisfied with the current rate of the current pace, one might be able to stay ahead.

I think the process we have outlined is credible, I think it works. In the eyes of many, it probably is not moving at a pace sufficient to what their goal would be as it relates to timely reregistration.

Senator WILSON. I think in a way we have a difference of opinion here, because whether or not it is moving at a sufficient pace depends very largely on whether or not failing to move at a more rapid pace poses an unacceptable risk.

With reference to my question to you earlier, you are saying in effect that it is the judgment of EPA that you're dealing in an area of acceptable risk presently and that, therefore, there need not be a concerted effort to accelerate the process of review?

Dr. MOORE. Harking back, some of the comments in Senator Leahy's opening statement I think fit in. To the degree that opinion polls show that 75 percent of the respondents put pesticides and concern about pesticide residues on food as a concern that they have, suggests that, indeed, one might want to look at alternate measures to either accelerate the process or other things of that sort so that they then have greater faith in the outcome of an Agency, such as EPA in this area. And we can put that issue to rest, or at least drop it from 75 percent down to something which is more reasonable.

To the degree that you want to do that, I think we've got to have more resources to get it done at a faster pace. There's no question about that.

Senator WILSON. Mr. Chairman, it seems to me that our concern here ought to be with what is an acceptable risk, and that we should, when we are satisfied that we know what that is, deal with the question of the resources available, not only to EPA, but perhaps even more significantly to the inspecting agencies, to the agencies that are required to actually implement whatever standards are adopted.

And I don't know that we have received any testimony on that. But it seems to me that is necessarily the implication of this whole line of inquiry by the committee.

The CHAIRMAN. Well, I'm not satisfied with the current rate. I look at these and I think that spending nearly a decade investigating EBDC's is not fast enough by any means. I will have a number of questions so that we can have a complete picture of how EPA is dealing with these high risk pesticides.

high risk pesticides.

[Senator Leahy's followup questions can be found on page 141.]

The CHAIRMAN. I think that there are some people, especially in the past—and I certainly do not include you in this regard, Dr. Moore—who were very happy to see the funding cut back for regulation of these chemicals and of these pesticides, because if we can't investigate them, we can't do anything about them and it doesn't make any difference what the law is. If you don't have the wherewithal, you don't have the people, and you don't have the resources to reinforce the law, you might as well not even have the law.

I think there were some who felt that we had some good, tough environmental laws in this area. That concerns me very, very much.

I talked to you about this earlier. I want to know how we are dealing with these high-risk pesticides. I think getting tougher FIFRA legislation is a necessity. It is certainly a priority of mine. I intend to work to do that. I want to have a good bill, though. I want to have a realistic bill, one that is enforceable and workable, and adequately funded within the resources, scientific and otherwise, that we have.

I am going to work hard to get just such legislation. And I will work very hard with EPA and with everyone else who will be involved with this. And I would, of course, hope that EPA would do the same and work very hard with us.

Dr. MOORE. Senator, we look forward to it. As you know, there are a number of things in that statute that we have stated in the past could be changed that would allow us to have more output, even with the existing level of activity, if indeed some of these tripwires were taken out. To implement the recommendation that was in the report that suggested that one could move on a negligible-risk approach between raw and processed foods, for example, is something we could start. But I suspect that if we tried to implement that, we might be at some legal risk given the current language that is in statutes.

The CHAIRMAN. I understand that, and I realize there are some changes that should be made. We will work on figuring out where those should be made. I think your testimony and the testimony of the panel before you emphasize that we are sadly lacking in some of the resources that we need to enforce the law even as it is written.

And I am very, very concerned about the philosophy that went behind the removing of some of those resources.

Dr. Moore, thank you very much. Senator Pryor, do you have anything further?

Senator PRYOR. No.

The CHAIRMAN. Thank you very much and I appreciate you being here. I also appreciate very much the amount of time that you and Mr. Thomas spent with me and with the Senate Agriculture Committee staff in preparing for these hearings.

Our final witnesses today are on a panel. We have Dennis R. Heldman, the executive vice president for scientific affairs, National Food Processors Association; Edward Dunkelberger, legal counsel, Covington & Burling, representing the National Food Processors Association; Lawrie Mott, senior staff scientist, National Resources Defense Council; and Al Meyerhoff, senior staff attorney, National Resources Defense Council.

The two groups who will testify have a total of 10 minutes available before we go into questions. Actually we will go until a quarter of the hour, which extends their time to about 13 minutes. You can divide it up any way you want. So, whoever speaks first should know that whatever amount of time you use, you all have only got 13 minutes total, but then that's it. After that we will go to questions. I just don't want you to feel any peer pressure from those waiting to speak.

Who would like to start? Please state your name for the record.

STATEMENT OF DR. DENNIS R. HELDMAN, EXECUTIVE VICE PRESIDENT FOR SCIENTIFIC AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION, ACCOMPANIED BY H. EDWARD DUNKELBERGER, JR., LEGAL COUNSEL, COVINGTON & BURLING

Dr. HELDMAN. My name is Dennis R. Heldman. My title is executive vice president for scientific affairs of the National Food Processors Association.

I am with the National Food Processors Association [NFPA]. Edward Dunkelberger from Covington & Burling is our legal counsel who is here to join me in answering questions.

The more than 450 food processor members of our association appreciate your allowing us the opportunity to appear here today, and comment on the report we have been discussing this morning.

I have submitted a prepared statement for the record. In the time allotted for me now, I would like to make a few comments about the report and our association.

Since 1906, our food processor members have supported the laboratories of the National Food Processors Association, which today consists of three "state-of-the-art" facilities, one here in Washington, one in Dublin, CA, and one in Seattle, WA.

As a scientific, technical, and highly regulated industry, we recognize the need to constantly evaluate the effectiveness of our industry's systems and legal and regulatory system in assuring that the food supply is safe. This is particularly true in light of developing science and technology.

In that spirit, we fully appreciate the work done by the National Academy of Sciences.

We think it is important to remember several points, with respect to the Academy's work, in order to assure the important discussions this work will trigger are most productive.

As repeatedly indicated in the NAS report and in comments by members of the committee that prepared the report, the purpose of this work was to come up with a method for managing risk. We look forward to the opportunity of examining this method in great detail. The report should not be mistaken for an assessment of risk, however. Numbers indicated in the report are highly theoretical.

The food supply is safe. We have heard that many times this morning. To draw any conclusions to the contrary is, by the committee's own admission, totally inappropriate.

Our analysis of the preliminary data we have submitted with our prepared statement leads to the following observations about material contained in the report.

One, tolerance levels for processed foods as used in the NAS report appear to be 100 to 1,000 times above actual residue levels, suggesting the extent of overstatement for oncogenic risk contained in the report.

Two, due to the overstatement of risks, we questioned the risk reductions that the NAS report maintains to be achieved. We feel that much of the risk that the report proposes to reduce does not actually exist.

Three, due to the negligible residue levels found in processed foods, the need to consider an alternative approach to pesticide regulation must be carefully evaluated.

I would like to take this opportunity to express the food processing industry's regret that it did not have an ample opportunity to contribute realistic residue data for use in the report. We feel that this would have led to a report that was much more meaningful and useful.

If this report does nothing else, it clearly indicates the need for information reflecting actual industry practices and conditions before any significant decisions regarding the current systems for regulating pesticides are made.

I want to record here the willingness of the NFPA to work in close cooperation with the EPA, the Food and Drug Administration, and the Department of Agriculture, and any other appropriate agencies to develop information that accurately reflects industry practices and conditions.

We have already been in touch with EPA and indicated our interest for exploring the need for further studies to develop appropriate data to address issues raised in the report.

Thank you for this opportunity to appear. We will be happy to answer any questions.

[The prepared statement of Dr. Heldman follows:]

TESTIMONY OF DR. D. R. HELDMAN BEFORE SENATE COMMITTEE IN AGRICULTURE, NUTRITION AND FORESTRY

My name is Dr. Dennis R. Heldman, and I am Executive Vice President for Scientific Affairs of the National Food Processors Association.

The National Food Procesors Association (NFPA) is a scientifically and technically based trade association representing nearly 600 companies including most of the major food processing companies in the US. About 450 of our member companies pack processed-fruits, vegetables, meats, fish and speciality products including canned, frozen, aseptic, dehydrated, pickled and other preserved foods. Other of our members manufacture food packaging and processing equipment, or provide supplies and services to the food processing industry.

We maintain three research laboratories, in Seattle, Washington, Dublin, California and here in Washington, DC in which approximately 120 professionals conduct research, product testing and methods development work for our member companies and the food industry.

The primary mission of our research laboratories has always been to help our members ensure the safety and integrity of the food products. For more than 40 years, work on pesticide residue chemistry, the effects of food processing operations on legally permitted residues, and the development and improvement of analytical procedures for detecting and studying pesticide residues has formed a significant component of our total research and effort.

My purpose in appearing here today is to introduce the committee to our work in this area, and to leave for the committee's records copies of published studies and recently collected data that will characterize the current state of our knowledge on the behavior of permissable pesticide residues in food preparative systems. These materials will explain how normal commercial food preparative operations remove major portions of the pesticide compounds that are permitted on raw agricultural crops. They will also illustrate our capabilities to further research any areas indicated by this investigation as needing additional information.

I want to record here our willingness to work in close cooperation with The Environmental Protection Agency, The Food and Drug Administration, The Department of Agriculture and any other interested regulatory state or federal agencies to obtain additional data on the behavior of pesticide residues, and to work with the agencies and with appropriate Congressional staff to improve administrative procedures for the regulation and control of the agricultural chemicals that our growers need to be able to supply us with our raw agricultural commodities.

Before getting into the subject of pesticide residues and their behavior in food preparative systems, however, I need to first document two critically important programs that have been a regular part of this association's work for many years.

Rather than rely upon sampling and analysis of raw and finished products to detect pesticide residues after they are present, the major effort of the food processing industry is directed toward the prevention of illegal or unnecessary residues through the inappropriate or excessive use of agricultural chemicals in crop production. These preventive measures are outlined in the NFPA's "Protective Screen Program."

THE PROTECTIVE SCREEN PROGRAM

The NFPA's Protective Screen, is a program to prevent illegal contamination of raw agricultural products with pesticide chemicals. Its detailed recommendations were adopted by the industry in 1960 and it is revised and updated as may be required by changes in the regulatory structure or industry experience with control chemicals.

For many years it has been published annually in a popular trade reference, "The Almanac of the Canning, Freezing, Preserving Industry". A copy of the protective screen program as it appears in the current copy of the almanac is submitted herewith for the committee's record.

ANALYTICAL METHODS

The Committee of Food Industry Analytical Chemists

Before one can have reliable information on the behavior of traces of pesticide compounds in food processing systems, it is essential that we have analytical procedures whose reliability has been established by testing in a number of competent and experienced analytical laboratories. The NFPA has had in place since about 1965 a committee of experienced analytical chemists who, working with staff scientists in the NFPA's own laboratories conduct a number of tests each year to establish the reliability and to document the expected variability of the analytical procedures used to detect and measure pesticide residues and environmental contaminants or to measure important food constituents such as vitamins and nutrients. The committee annually studies any analytical procedures that may have some regulatory or quality control significance. Pesticide residue methods have been an important part of this work for many years. Committee members analyze and compare results on a wide variety of sample materials adjusting or advising against the use of analytical procedures that are found to be unreliable, and establishing for NFPA member use, a body of data that serves to define the state of the art with respect to the variability of analytical methods in use in the food processing industry.

I am providing for the committee's records, illustrative examples of this work as published in recent Annual Reports of our research laboratories.

BEHAVIOR OF PESTICIDE RESIDUES IN FOOD PREPARATIVE SYSTEMS

This association has carried out a number of studies to clarify the behavior of permissable pesticide residues in food preparative systems. I emphasize again that the industry's protective screen program is designed to prevent the occurrence of illegal or unnecessary levels of agricultural control chemicals on food crops reaching the food processing plant. Our experimental work was designed to study the effects of normal product washing, blanching and processing procedures on within- tolerance residues. Of course, we were also interested in maximizing residue removal, to the extent that this was feasible and practical in commercial operations. This work covered a period of some four to six years, and much of it is published in the scientific literature.

A review published in volume 29 of Residue Reviews titled "Canning operations that reduce insecticide levels in prepared foods and in solid wastes", covers most of this work. The title of the paper refers to canning operations that reduce insecticide levels. (Our organization was then the National Canners Association.) Of course the unit food preparative operations described in the report such as product washing, blanching and peeling, are applicable to those operations in other forms of processing.

In this experimental work we attempted to duplicate field spraying operations and commercial preparative conditions as closely as possible, generally with the minimum label recommended time interval between pesticide treatment and harvest. The experiments were designed to obtain a field weathered pesticide residue on each experimental crop that was as close as possible to the appropriate tolerance for the pesticide and crop under test.

The article shows, for example 71% of permissible malathion residues were removed by blanching. On spinach, 71% of the parathion residue and 60% of the diazinon residue were removed by washing and blanching. Of course the nature of the pesticide chemical, the crop on which it is sprayed, and the extent to which the residue is weathered are all very important conditions affecting the amount of removal.

More recently, our laboratories were retained to participate in a study of the behavior of benomyl residues during their preparation and processing of tomatoes, oranges and apples. These results are summarized in Table I. "Behavior of Benomyl in Food Processing Operations".

Note that in tomatoes, where the current tolerance for benomyl is 5 ppm, the washing operation removed 80% of the residue. The preparation of tomato paste, which involves in this instance more than a four-fold concentration of tomato solids, resulted in only a two-fold concentration of the benomyl residue. It is important to note that in this instance, the residue in the paste, a concentrated product, was still approximately one-tenth of the residue permitted in the raw agricultural product.

These data also show that this pesticide has a tendency to accumulate in the orange oil, where it is still below the raw product tolerance.

The theoretical possibility that residues permitted on the raw agricultural product can become concentrated during food processing operations has been a topic under discussion among those interested in pesticide residue chemistry, as well as those charged with the responsibility for administering and regulating the use of agricultural chemicals. As this committee knows, the concentration of a pesticide residue permissable under a "408 tolerance" to levels exceeding the 408 tolerance would trigger the necessity for a "409 tolerance" and its attendant food additive considerations. This was once a theoretical possibility of more than a little interest in the food industry, where the concern was that a residue permissable on the raw agricultural product, might result in an illegal processed product by reason of its inadvertent concentration during food processing operations.

While this remains an active theoretical possibility, the NFPA knows of no instance under actual commercial or field test conditions in which the actual need for a 409 tolerance has been triggered by concentration phenomenon. We remain actively interested in researching this question and we will be most interested in exploring with the EPA opportunities for cooperative research on this subject. Based on our experience to date, however, we must conclude that with very few exceptions, the administration of pesticide regulations utilizing existing or analogous 408 tolerances on the raw agricultural products with existing pass through interpretations, would not result in a hardship to the food processing industry. Exhaustive research on this point is likely to turn up a few exceptions, but our experience suggests that they will be rare.

INDUSTRY AND GOVERNMENTAL MONITORING PROGRAMS

The studies described in the preceeding section were experimental programs designed to simulate as closely as possible the actual commercial conditions present in the application of agricultural chemicals and their subsequent behavior in commercial food processing operations. Many food processors routinely check incoming raw products to insure that the procedures they use for preventing the occurrence of illegal or excessive residues are working, and that those supplying them with raw materials are in compliance with the label directions specifying the conditions of use of agricultural control chemicals.

A word about the philosophy behind the application of these monitoring efforts is in order.

Analytical work to detect and quantitatively estimate pesticide residues is notoriously expensive. Therefore it makes little economic sense for either industry or government agencies to expend large sums of money and devote limited laboratory resources to the analysis of large numbers of random samples. On the contrary, the philosophy behind the application of these monitoring efforts in industry as well as in government is to selectively sample those situations having the highest probability of occurrence of illegal unnecessary pesticide residues.

If a compound is not registered for use on a crop, it makes no sense to order analytical work for that compound on samples of the crop unless there is information that compound has been used by mistake or illegally. Virtually all agricultural control chemicals are now used by licensed commercial operators subject to careful scrutiny by regulators. When instances of inadvertent or illegal use of chemicals come to light, samples of the crop are collected and analyzed, usually by both interested industry as well as regulatory agencies. Indeed, some of the data submitted with this testimony were obtained under such circumstances.

In many instances, compounds are registered for use on a specific crop, but are not actually used in the locality under consideration. Here again, it makes little economic sense to expend expensive analytical effort looking for compounds which company field men know by reason by close contact with their growers, that such materials have not actually been used. Most companies wisely spend their analytical efforts checking on situations where they are most likely to find difficulties.

Much of the analytical data in the accompanying table have been obtained under the above circumstances, and they should not be interpreted as truly representative of the "average" conditions for the products sampled. They are in fact quite likely to be biased toward situations in which residues are expected to be found. Table II summarizes the results of more than 17,000 tests. It includes results from a number of companies and other monitoring programs concerning a large number (about two or three hundred) pesticides.

A "positive" result means only that a detectable trace of the compound, or one of the compounds under test, was detected.

The one major program devoted to a random sampling of pesticides and environmental contaminants in the American dietary is the Food and Drug Administration's Market Basket survey. This committee is no doubt familiar in a general way with this monitoring program. It is based upon the diet of a segment of the population deemed to be the heaviest eaters, namely 19 year old males. Composite samples of a typical diet are analyzed for pesticide and environmental contaminants.

In our view, this type of monitoring program is the best possible compromise, in that it provides a useful indication of the traces of pesticides and environmental contaminants to be found in a diet without the prohibitively expensive effort of analyzing thousands of samples for hundreds of theoretically possible contaminants. We would like to record our support for a continuation of these efforts on the part of the Food and Drug Administration.

MONITORING OF IMPORTS

There is no food producing country where agricultural products are subject to the intense regulatory scrutiny that is exercised in food production in the United States. It is therefore reasonable to expect, and available data support the conclusion that imported products are more likely to contain higher levels of residues and that the incidence of illegal residues will be higher than in domestic crops subject to U.S. regulatory systems. A heavy burden of sampling and analysis is therefore placed upon the Food and Drug Administration and the other regulatory agencies charged with the responsibility of monitoring incoming raw agricultural and finished food products. The FDA's resources available for this effort are traditionally overtaxed. An application of the principle of expending analytical resources in those areas where problems are most likely to be encountered would dictate that more resources to be devoted to monitoring products at the border.

CONCLUSIONS

The record amply demonstrates that the vast majority of the permitted within tolerance pesticide residues are removed by normal commercial food preparative operations.

Available monitoring data demonstrate that the process food supply is remarkably free of illegal or unnecessary residues of agricultural control chemicals.

This record notwithstanding, we solicit any opportunity to work with the EPA, FDA or other responsible regulatory agencies on cooperative research projects that will answer any remaining questions about the behavior of pesticide residues in food preparative systems, and especially to explore in detail the need for 409 tolerances arising from residue concentration phenomenon in food preparative systems.

Attachments follow:

TABLE I

Behavior of Benomyl in Food Processing Operations

Treated Food Form	Tomatoes	ppm Benomyl Oranges	Apples
(Raw Product Tolerance)	(5.0)	(10.0)	(7.0)
Raw	1.76	3.28	1.06
Raw Washed	.31	.75	.89
Juice Canned	.25	.07	.31
Puree	.02	-	-
Paste	.57	-	-
Catsup	.03	-	-
Oil	-	2.51	-
Molasses	-	.34	-
Sliced	-	-	.10
Sauce	-	-	.18

TABLE II

Summary of Pesticide Residues in Foods

PRODUCT	RAW No. of Samples	RAW No. of N.D.	RAW No. of Positives	PROCESSED No. of Samples	PROCESSED No. of N.D.	PROCESSED No. of Positives
Tomatoes	4506	4322	184	7288 [1]	7239	49 [5]
Oranges	159	0	159 *	276 [2]	276	0
Potatoes	89	85	4	586 [3]	586	0
Beef	84	84	0	-	-	-
Lettuce	1814	1327	487	-	-	-
Apples	13	13	0	-	-	-
Peaches	1	1	0	-	-	-
Pork	44	44	0	-	-	-
Wheat	5	5	0	-	-	-
Soybeans	48	48	0	-	-	-
Beans	150	138	12	-	-	-
Carrots	18	18	0	-	-	-
Chicken	9	9	0	-	-	-
Corn	41	41	0	-	-	-
Grapes	6	6	0	-	-	-
Peanuts	12	12	0	11 [4]	11	0
Juices (other than orange)				2108	2058	50 [5]

N.D. = Non Detectable

- = no data

1. Tomato juice, tomato paste, tomato soup, catsup, vegetable juice
2. Single strength juice and concentrates
3. Potato chips, potato flakes, potato granules
4. Peanut butter
5. All within tolerance

* = Residue required by state of Florida to control canker; residue in peel only

Sources: National Food Processors Association
Florida Department of Agriculture and Consumer Services

PREVENTING CONTAMINATION OF THE RAW PRODUCT

NATIONAL FOOD PROCESSORS ASSOCIATION PROTECTIVE SCREEN PROGRAM

a program to prevent illegal contamination of raw agricultural products with pesticides

(Revised and updated April 1980, February 1983)

I. OBJECTIVE

To provide assurance of the safe and effective use of pesticides[1] in the production of processed foods.

II. THE PROTECTIVE SCREEN

A protective screen against illegal pesticide contamination of raw agricultural products, maintained by food processors with their growers' cooperation, is essential to the production of wholesome food products. Assurance that raw products are free of illegal pesticide residues at the time of delivery to processing plants is a primary step in assuring the wholesomeness of processed foods delivered to consumers.

A. NFPA POLICY ON THE USE OF PESTICIDES

To protect the integrity of processed foods and to assure their freedom from illegal pesticide residues, the National Food Processors Association (NFPA) has adopted certain specific recommendations which are made known to all food processors in the United States.

These recommendations are based on the requirements of the Federal Food, Drug and Cosmetic Act (FD&C Act) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and implementing regulations of the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Food Processors need not approve the use of all pesticides which have been or may be registered for use on each crop, but may, by agreement with the grower, put limitations on the use of certain pesticides, especially on those that in any way influence the flavor or quality of the crop being purchased.

The following is an outline of NFPA policy concerning the use of pesticides on processing crops:

(1) Processors of crops that have been treated, or produced on land that has been treated with any pesticide should be certain that such pesticide has been registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, or by a state for a special local need pursuant to section 24(c) of FIFRA.

(2) Each processor should be certain that the growers who supply his raw products are aware of the restrictions placed on the use of pesticides. It should be the further responsibility of each processor to make sufficient periodic contacts with his growers to assure himself that pesticides are being used in accordance with the directions prescribed in their labeling. A list of the pesticides acceptable to the processor may be furnished to his growers to assist them in complying with state and federal regulations.

3. Each processor should be assured that detailed records are maintained showing how pesticides have been used in the production of crops which are to be processed. The processor should be in possession of such records before the crop is harvested.

(4) Each processor purchasing crops under contract should obtain written statements from his growers that they will use only registered pesticides in a manner consistent with their labeling. According to the Federal Insecticide, Fungicide and Rodenticide Act as amended in 1978:

"The term 'to use any registered pesticide in a manner inconsistent with its labeling' means to use any registered pesticide in a manner not permitted by the labeling: Provided, That the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling, or (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling: Provided further, That the term also shall not include any use of a pesticide in conformance with section 5, 18 or 24 of this Act, or any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act: And provided further, That after

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[1] The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (1972) defines a "pesticide" as being "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant or dessicant." A "pest" is defined as being "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator (of the EPA) declares to be a pest."

March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion[2] specifically requires the use of definite amounts of dilution."

Processors purchasing crops on the open market should obtain written statements from the growers or sellers that if pesticides were applied, that only registered pesticides were used and that they were applied in a manner consistent with their labeling.

(5) Processors should participate in the development of educational programs on the proper use of pesticides in cooperation with federal and state agencies responsible for the enforcement of FIFRA, the extension service, producer organizations, and other interested groups.

(6) Processors of crops that have been treated, or grown on land that has been treated with any pesticide in a foreign country should be certain that such pesticide has been used in accord with regulations and label directions established in that country. In a country where use of a particular pesticide is not regulated and/or directions for use are not listed on the pesticide label, acceptance of the pesticide use should be guided by regulations and label directions established for the same or a similar use in the U.S. or in another country having a pesticide regulatory program.

(7) Processors of foods produced in foreign countries should be certain that residues in the foods comply with tolerances established in the country where the foods are produced and in the countries where the foods will be consumed. In countries where tolerances are not required, residues should conform with tolerances established in the U.S. or in another country having a pesticide regulatory program, or with tolerances established by an international body such as the FAO/WHO Codex Alimentarius Commission.

B. WRITTEN ASSURANCE THAT PROCESSING CROPS ARE FREE OF ILLEGAL PESTICIDE RESIDUES

Processors should obtain written statements from growers and other raw product suppliers stating that only registered pesticides were used, and that no illegal or unsafe residues remain on the crops. The written statements may be adapted to the practices of each food processor and to the particular circumstances under which he operates. NFPA recommends, however, that the statement be drafted in accord with the following language:

Contract Crops - "The grower agrees to use only those pesticides in the production, transportation and storage of the crops that are registered by EPA or by a state for a special local need pursuant to section 24(c) of FIFRA, and that the pesticides will be used in a manner not inconsistent with their labeling. The grower warrants that the crop, when delivered to the buyer, will contain no pesticide residue which is unsafe within the meaning of section 408(a) of the Federal Food, Drug, and Cosmetic Act."

Open Market Purchases - "The grower (seller) warrants that all pesticides used in the production, transportation and storage of the crop were registered under FIFRA, EPA or by a state for a special local need, and were used in a manner not inconsistent with their labeling. The grower (seller) further warrants that the crop contains no pesticide residue which is unsafe within the meaning of section 408(a) of the Federal Food, Drug, and Cosmetic Act."

It should be clearly understood by the processor that no form of guarantee from a grower or seller can operate to relieve the processor from his liability under the Federal Food, Drug, and Cosmetic Act. If the processor sells foods that are adulterated or misbranded - including foods that contain unsafe pesticide residues or other food additives - he remains subject to criminal prosecution, injunction, and seizure of his products, whether or not he has a guarantee from his supplier. The written statements recommended above serve primarily as a means of informing the supplier of his responsibility, and as evidence of the processor's good-faith efforts to comply with the law.

C. INFORMATION FOR PROCESSORS AND GROWERS ON THE LEGAL USE OF PESTICIDES

The NFPA Environmental Affairs Division through its Crop Protection Newsletter will keep the food processing industry informed on the development and promulgation of regulations governing the use of pesticides. Processors should look to their cooperative extension service or other designated authority for recommendations on measures to be used for control of specific pests in crops being grown for processing.

Authoritative information on pesticides registered by the Environmental Protection Agency is contained in a data system titled "Pesticide Product Information on Microfiche (PPIOM)." The system is designed to assist individuals in answering a wide range of pesticide-related questions and permit pesticide users to make use of EPA's Office of Pesticide Programs computer-based information. The information includes product names, manufacturers, active ingredients, tolerances for residues, and site and pest information for particular products and active chemical ingredients. PPIOM is updated and published as a new edition each spring (the 8th edition was published in April 1983). Microfiche sets may be ordered by title from the Subscription Department, National Technical Information Services, 5285 Port Royal Road, Springfield, Virginia 22161.

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[2] Pesticides may not be used at more than label dosage (46 FR 14965-67, March 3, 1981 and 45 FR 3316-24, January 17, 1980).

A computer-based data resource, the National Pesticide Information Retrieval System (NPIRS), is available by subscription to individuals or firms with compatible computer systems. The NPIRS contains much of the same information as PPIOM, as well as pesticide data from participating states. Information about subscriptions is available from National Pesticide Information Retrieval System (NPIRS), Entomology Hall, Purdue University, West Lafayette, Indiana 47907.

The cost of purchasing the microfiche (PPIOM) or subscribing to the computer-based information system (NPIRS) may be prohibitive for small processors. However, an alternative source of reliable information on registed pesticides is not readily available.

III. A PROGRAM TO PREVENT PROCESSING OF RAW PRODUCTS CONTAINING ILLEGAL PESTICIDE RESIDUES

Sophistication in analytical procedures in recent years has made it possible to monitor incoming raw products and ingredients for a greater variety of potentially objectionable substances at higher levels of sensitivity than has been possible in the past. Analytical capabilities have evolved to encompass greater numbers of substances at exquisite levels of sensitivity to meet the requirements of more complex regulations and demands for information on the microcontaminants present in our food supply. Close industry cooperation through technically-oriented trade association groups can assist in meeting these challenges at the lowest possible cost to industry and the consumer.

A. RAW PRODUCT AND INGREDIENT MONITORING

It is important to recognize that monitoring or testing programs cannot serve as the sole or even primary assurance that finished food products will be free from illegal pesticide residues. The emphasis must be on preventing the occurrence of contamination rather than reliance on its detection after the fact. A major portion of the preventive effort must be directed toward the discovery and avoidance of situations in which illegal residues or contamination are likely to occur. The pooling of industry experience and expertise in these areas is an important and effective procedure for enhancing consumer confidence in the food supply.

Analysis of raw products and other ingredients can serve as an extremely important part of the screen of preventive measures. However, analytical efforts are extremely expensive. Unnecessary analyses can only add to the nation's food bill without providing a commensurate dividend of confidence in the food supply.

It is not practical to provide generalized directions on the extent to which raw product monitoring should be carried out. Each food processor must evolve his own system in the light of his raw product requirements and food manufacturing operations. Experience has shown changing patterns of pesticide residues. Pesticide usage is changing as use of the more persistent pesticides is restricted or discontinued in favor of less persistent agents. Sampling and analysis programs should be flexible enough to focus quickly on new areas of potential concern.

B. FOOD PROCESSING INDUSTRY COOPERATIVE EFFORTS

Since their inception in 1913, the Research Laboratories of the National Canners Association (now NFPA) have worked closely with their technical counterparts in the regulatory agencies as well as those within industry to focus attention on problems of common concern. This tradition of coordinated industry-wide programs to meet special technical problems is especially well illustrated in the industry's effort to monitor ingredients and raw and processed products for illegal pesticide residues and other objectionable contaminants.

For many years the NFPA Research Staff has operated a Committee of Canning Industry Analytical Chemists for the express purpose of sharing and enhancing the analytical expertise required to operate effective monitoring programs within the industry. This group meets at least twice yearly to discuss problems in the application of analytical methodology, and to anticipate and avoid potential pesticide residue or other contaminant problems.

An important feature of this cooperative effort has been the operation of a collaborative analytical testing system that enables participating laboratories to maintain the highest possible degree of effectiveness in their monitoring programs. Sample materials presenting special analytical problems of importance are shared among cooperating industry laboratories. Analytical standards are also shared when appropriate. The results of monitoring programs and cooperative tests are discussed at the frequent meetings and analytical difficulties are resolved by pooling available expertise in the appropriate scientific specialties.

Information on potential problem areas is also shared so that monitoring programs can be adjusted accordingly.

IV. USE OF PROCESSING BY-PRODUCTS FOR ANIMAL FEED

The Environmental Protection Agency (EPA) has authority, under section 408(b) of the Federal Food, Drug and Cosmetic Act (FD&C Act), to establish tolerances for pesticides in animal feeds (21 CFR §§193, 561; 40 CFR §180). It is a violation of the FD&C Act to introduce into interstate commerce processing by-products for animal feed use which contain illegal pesticide residues. Similarly, most state food laws prohibit intrastate distribution of animal feeds which contain illegal pesticide residues. FDA does not permit blending of over-tolerance animal feeds with under-tolerance feeds to achieve an acceptable pesticide residue level. Some states, such as California, permit animal feed blending under strict supervision.

Any processor who sells or employs processing by-products for animal feed use should take measures to assure that the feed does not contain illegal pesticide residues. Where there is a tolerance for a particular pesticide in animal feed, the processor should assure compliance with the specific restrictions of the tolerance and pesticide labeling (*e.g.*, prohibition of use of a treated crop for use as a feed for dairy animals). Where processing by-products are sold or otherwise provided (*i.e.*, at no cost or for a hauling fee) to haulers and not intended for animal feed use, the processor should require written assurances from the hauler that the by-products will not enter animal feed channels.

CHEMICAL ANALYSIS:

DETERMINATION OF ETHYLENE DIBROMIDE IN FOOD: COLLABORATIVE STUDY

For many years ethylene dibromide (EDB) has been the most effective and economical pesticidal fumigant for use in citrus fruits and agriculture products for storage. EDB is a heavy volatile liquid with a chloroform odor. The National Cancer Institute reported that EDB is very toxic and carcinogenic to rats. EPA has now banned all EDB use as a pesticide, and established official tolerances for EDB residues in grain and grain-based foods.

These tolerances are 900 ppb in raw grain, 150 ppb in intermediate food such as flour and 30 ppb in ready to eat foods such as cold cereal and bread. Some states, however, have set their own standards which are more strict than federal standards. The state of Maine, for example, established 30 ppb in raw grain, 5 ppb for ready-to-eat grains and 0 ppb for baby foods. The state of Massachusetts set their tolerance at 1 ppb residue across the board, which is the toughest standard in the nation. Laboratories of regulatory agencies and the food industry are now examining food products for the levels of possible contamination. The NFPA has spent considerable time to improve an existing analytical method and has tested a number of samples for our affected member companies.

In the NFPA laboratories EDB is determined by a method developed by Rains and Holder (1981) with some modification. The method includes steam distillation of the sample in a water-hexane mixture followed by injection of the dried hexane distillate on a column of a gas chromatograph equipped with an electron capture detector. The procedure is straight forward and simple. The NFPA modification requires sample blending for 2 minutes with a hexane-water mixture prior to the distillation and recommends addition of diluted sulfuric acid, if needed, to the sample to subside excessive foaming.

This year, the NFPA Committee of Food Industry Analysts (CFIA) carried out a collaborative study on EDB analytical methods. CFIA consists of chemists of NFPA member companies and meets twice a year to discuss the results of collaborative studies and considers ways to improve analytical techniques. The objectives of this study were to obtain data on interlaboratory variability of the methods and to determine the accuracy and precision of the methods at low levels.

We purchased from a local supermarket samples of pancake mix, quick grits, corn meals and cake mixes. These samples were tested and separated according to various levels of EDB. Collaborators received each of the five samples in duplicate, ten samples in all. Each participating laboratory was asked to test each sample by the method currently being used in that laboratory and to test each sample by the method supplied by NFPA. Most laboratories used the distillation procedure and measured EDB by GC or GC-mass spectrometry.

Table 15 shows the results from three sets of samples containing very low levels of EDB residue. Samples A and F are blind duplicates. The sample was a pancake mix that contained EDB at less than 1 ppb by our initial analysis. Results were largely the same on the samples regardless of the method used. Twenty-four values were reported by laboratories using their current method. Six values were over 1 ppb. Eighteen values were less than 1 ppb. Twenty values obtained using the NFPA method were reported. Five values were over 1 ppb. Because of the variety of ways the data were reported at these low levels no statistical analyses were performed.

Samples C and E are duplicates. The sample was a corn meal that contained 1 ppb by our initial analysis. Most laboratories reported the samples to contain 1 ppb or less EDB residues. Samples D & H are also duplicates. This quick grits sample contained less than 1 ppb by our analysis. Only one laboratory reported values above 1 ppb. Attempts were made to collect as many data as possible at these low levels because 1 ppb was considered to be critical at the time.

Sample I (**Table 16**) was a golden cake mix that contained EDB residue at 4-5 ppb. Eleven laboratories reported values obtained from their method and eight laboratories from NFPA methods. Three laboratories reported abnormally high values obtained with both methods. These values were not used in the statistical calculations. The coefficient of variation at this level was considered very good regardless of the method used.

Duplicate sample J showed similar results. The same number of high values were reported from three laboratories and they were excluded from the statistical calculation. We suspect that this was due to the problem of homogeneity in the samples. Coefficients of variation obtained by the current and NFPA method are considered to be close to each other and good.

Sample B (**Table 16**) was a white cake mix which contained about 8 ppb in our analysis. Twelve laboratories reported values obtained from the current method and eleven laboratories by the NFPA method. Abnormally high values and outliers were again excluded in the statistical calculation. The statistics appear to be very good at the level indicated. The coefficient of variation calculated on the data obtained by the NFPA method (16%) was somewhat lower than the coefficient of variation obtained when laboratories used their own method (26-27%). Equally good results were obtained from duplicate sample G. The coefficient of variation was again good by both methods. The NFPA method again showed a somewhat lower coefficient of variation.

Table 15—EDB (ppb) in food: collaborative study

Samples	Current Method	NFPA Method
A	N.D.-3.8	N.D.-4.4
F	N.D.-4.2	N.D.-1.5
C	N.D.-4.3	N.D.-4.4
E	N.D.-4.8	N.D.-3.9
D	N.D.-3	N.D.-2.0
H	N.D.-2.9	N.D.-1.8

N.D. = none detected

Table 16—EDB in cake mix samples

Sample I (ppb EDB)

	Current Method	NFPA Method
Mean	4.0	3.6
S.D.	0.67	0.55
CV%	16.8	15
# Lab	11	8

Sample J (ppb EDB)

	Current Method	NFPA Method
Mean	4.7	3.8
S.D.	0.8	0.83
CV%	17.7	22
# Lab	11	8

Sample B (ppb EDB)

	Current Method	NFPA Method
Mean	8.7	7.3
S.D.	2.32	1.17
CV%	27	16
# Lab	12	11

Sample G (ppb EDB)

	Current Method	NFPA Method
Mean	9.3	8.6
S.D.	2.4	1.39
CV%	26	16

This EDB collaborative study was found to be rather difficult because of problems of volatility of the residue and homogeneity of the samples. The performance of the laboratories in the determination of EDB was satisfactory for the samples containing the levels of 4 to 10 ppb. The interlaboratory coefficient of variation was 15 to 27% for these samples. Slightly lower coefficients of variation were observed for the NFPA method than when laboratories used their current methods. Based on our results the methods currently used by industry are not accurate and precise enough for the determination of EDB residues in food at low levels around 1 ppb. This may be due to peak interference in GC analysis or to the presence of the residues at levels near the detection limit of the method.

We would recommend, therefore, any values less than 1 ppb be reported as less than 1 ppb.

(For further information contact E.S. Kim in Washington, D.C.)

REFERENCES

Rains, D.M. and Holder, J.W. 1981. Ethylene dibromide residues in biscuits and commercial flour. J. Assoc. Off. Anal. Chem. 64:1252.

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1984 ANNUAL REPORT
NFPA RESEARCH LABORATORIES

The CHAIRMAN. Thank you very much. Ms. Mott.

STATEMENT OF LAWRIE MOTT, SENIOR STAFF SCIENTIST, NATURAL RESOURCES DEFENSE COUNCIL, ACCOMPANIED BY AL MEYERHOFF, SENIOR STAFF ATTORNEY, NRDC

Ms. MOTT. Good afternoon.

I am Lawrie Mott with the Natural Resources Defense Council.

The National Academy of Sciences [NAS] study, "Regulating Pesticides in Food—the Delaney Paradox," clearly illustrates the risks posed by pesticide residues in food. The report estimates that approximately 1.46 million cases of cancer will occur in our lifetimes from exposure to residues of only 28 pesticides in our food supply. In fact, 96 percent of these cases may develop from just 12 fungicides, herbicides, and insecticides. This startling estimate of dietary risk posed by carcinogenic pesticides may actually understate the full risk because it is based on only 28 chemicals. There are many more carcinogenic pesticides in our food. The Federal program that regulates pesticides in food has been routinely criticized in the past, but never before has the true impact of these deficiencies been so clearly demonstrated. The NAS report underscores the need for immediate and fundamental reform of the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA] in order to protect the public from the hazards of pesticide residues in food.

All consumers are exposed to pesticide residues in food, on a regular basis. Because the public has no way of knowing whether these chemicals are present in their food, laws and regulatory programs are critical for protection from involuntary exposure to this potential hazard. Unfortunately, numerous congressional and Government reports, over the last decade, have suggested that these are serious inadequacies in the existing programs that regulate pesticides. In particular, several of these reports have suggested that the current EPA and FDA programs do not adequately protect consumers from pesticides in foods.

I will briefly discuss some of these problems.

EPA tolerance levels may permit unsafe levels of pesticides in food. Many EPA tolerances have been established at levels that allow unsafe, unnecessarily high amounts of pesticide residues in food. Often, tolerances are established without sufficient toxicological data to assure that the levels chosen are safe for human exposure. In some cases, when data do exist, they are inadequate, invalid, or even fabricated. Further, when developing tolerances, EPA relies on arbitrary assumptions about what constitutes an average diet and what safety factors should be used. Inert ingredients and other chemicals of toxicological concern that may leave residues in the food are not considered in tolerance setting.

Last year, GAO again reported on the inadequacies of EPA and also FDA's programs to regulate pesticides in food. In particular, GAO criticized the Food and Drug Administration's laboratory methods for their inability to detect pesticides in food. Approximately 500 pesticides may leave residues in our food, but FDA cannot routinely detect half of those chemicals and, at best, 40 percent of the pesticides that FDA has identified as posing a moderate to high health hazard cannot be detected.

And further, in some cases, it took FDA 28 calendar days to obtain the results of their sample analysis for pesticide residues in food. So, in other words, by the time they actually received their laboratory results and were ready to take any enforcement actions, the food had already been consumed.

As a case in point, I would like to bring up some issues on the EBDC's that were discussed earlier this morning. You talked about the family of fungicides that account for approximately 30 million pounds of fungicides used in this country on an annual basis. A third of all fruits and vegetables are treated with these fungicides. They account for about 57 percent of fungicides used worldwide. They are used extensively on wheat, potatoes, citrus, tomatoes, apples, and other crops. However, FDA cannot even routinely detect residues of these chemicals in our food.

You talked about EPA initiating a special review of these chemicals in 1977 because they were concerned about their ability to cause cancer and birth defects. A metabolite of the EBDC's called ethylenethiourea [ETU], which is actually formed when the food is processed or cooked and concentrates when the foods are prepared, is carcinogenic. EPA has called it a probable human carcinogen and, in fact, the NAS report estimates that 1.6 excess cancer cases for 1,000 individuals exposed will occur as a result of the EBDC's residues in food.

You talked about the litigation brought against EPA in 1983 by my organization and the AFL-CIO, because we believe that EPA inappropriately removed those chemicals from the special review after a series of private meetings with the manufacturers of those substances.

NRDC agreed in the settlement of that litigation that EPA would complete its reassessment of all of the EBDC's by December 31, 1986. On December 30, 1986, we received a letter from EPA requesting an extension of the deadline for the reassessment of these chemicals for over 3 years, until March 30, 1990. And the reason that they needed that reassessment was because, and this is a direct quote from their December 30 letter, "EPA still lacks much of the necessary data" for completing the EBDC's risk assessment. That is what they told you was the reason they took the chemicals out of the EBDC's, out of the special review in 1982. They are still making that statement over 4 years later and they are claiming they need an additional 3 years, actually over 3 years, to complete that reassessment.

Now, let me discuss why I believe that, unfortunately, the NAS report may understate the risk from cancer-causing pesticides in food. There are six reasons why the risk may be understated.

First, pesticide residues occasionally are actually higher than established tolerances. According to recent GAO reports, approximately 2 to 4 percent of the foods sampled by FDA contained pesticide residues that exceed tolerance levels. The violation rate may be even higher because FDA's routine laboratory methods can only detect about half the pesticide chemicals that may leave residues in food.

Second, NAS estimated the cancer risk posed by only 28 food use pesticides. In fact, the NAS report identifies an additional 27 cancer-causing chemicals, but they did not include any risk assessment.

Third, the NAS report understates the risk of cancer from pesticides in our food because it focused only on active ingredients. Pesticide products contain both active and inert ingredients. Inert ingredients, although they are not active against the pests, may still be a toxicological concern. EPA has identified 55 hazardous inerts, and 15 of these are carcinogens used on food. They may be leaving residues in our food supply. Those food use carcinogenic inert ingredients are not addressed in the NAS report.

Fourth, the NAS report did not consider all the dietary risks posed by carcinogenic pesticides. Some of these chemicals have contaminated drinking water, and this route of exposure was not included in the NAS risk assessment. For example, alachlor has been found in both surface and ground waters that are drinking water supplies. Atrazine, a widely used herbicide which was not included in the actual numerical risk assessment, but was discussed briefly in the report, has also been detected in drinking water.

Fifth, the NAS report may understate the risk because it does not consider the possibility of synergism or enhanced carcinogenicity, that can occur from simultaneous exposure to pesticides.

Finally, in developing the cancer risk estimate, NAS used average estimates of food consumption. In other words, even though the more up-to-date tolerance assessment system—with its capacity to estimate dietary consumption patterns for 22 subgroups of the U.S. population—was used, NAS did not incorporate those specific subgroup estimates into its report. This is of particular concern because children may consume such larger amounts of certain foods. For example, toddlers ingest 16 times more milk products, 11 times more fresh bananas, 10 times more peanut butter, and 6 times more apples than the average adult.

And I would also like to note that in the appendix to the report, the NAS states that even using these average statistics, they may have underestimated the dietary exposure for 45 percent of the American population.

[The prepared statement of Ms. Mott follows:]

Prepared Statement of Lawrie Mott, Senior Staff Scientist,
Natural Resources Council (NRDC), May 20, 1987

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I. INTRODUCTION

I am Lawrie Mott, senior staff scientist at the Natural Resources Defense council (NRDC). With over 75,000 members and supporters, NRDC is a national, nonprofit environmental organization dedicated to the protection of public health and the environment. NRDC has long sought more effective government regulation of pesticides. In particular, we have focused extensively on the problem of pesticides in the food supply.

The National Academy of Sciences (NAS) study Pesticides in Food: The Delaney Paradox clearly illustrates the risks posed by pesticide residues in food. The report estimates that approximately 1.46 million cases of cancer will occur in our lifetimes from exposure to residues of only 28 pesticides in our food supply. In fact, 96 percent of these cases may develop from just 12 fungicides, herbicides, and insecticides. This startling estimate of the dietary risk posed by carcinogenic pesticides may actually understate the full risk because it is based on only 28 chemicals. There are many more carcinogenic pesticides in our food. The federal program that regulates pesticides in food has been routinely criticized in the past, but never before has the true impact of these deficiencies been demonstrated. The NAS report underscores the need for immediate and fundamental reform of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) in order to protect the public from the hazards of pesticide residues in food.

In 1984 NRDC issued two reports on pesticides in food. The first report, Pesticides in Food: What The Public Needs To Know contained the results of a year long investigation of pesticides in food and the adequacy of government programs that seek to protect consumers from these chemicals. As part of this examination, NRDC conducted a survey of fresh domestically-grown produce sold in San Francisco markets for pesticide residues. Ten different types of frequently-consumed fresh fruits and vegetables (broccoli, carrots, cucumbers, eggplant, lettuce, oranges, potatoes, spinach, strawberries and tomatoes) were collected for laboratory analysis.

Forty-four percent of the 71 samples contained residues of 19 different pesticides. Forty-two percent of the produce with pesticide residues contained residues of more than one pesticide. Three food samples had residues of four different pesticides. This is significant because rarely, if ever, does the federal government consider synergism when setting maximum allowable pesticide residue limits, or pesticide tolerances. The most commonly detected pesticide was DDT, even though its use had been banned 12 years earlier. The majority of pesticides detected in fruits and vegetables were found in amounts below EPA's tolerances. However, on closer inspection, many of these tolerances may not be sufficient to protect public health. For example, for some chemicals, the federal government lacked critical health tests to assure the safety of the tolerance levels; in other cases, tolerances were based on outdated assumptions concerning a typical diet.

II. CURRENT GOVERNMENT PROGRAMS DO NOT PROTECT CONSUMERS FROM PESTICIDES IN FOOD

We all have to eat, but does our food contain more than a safe amount of pesticide residues? All consumers are exposed to pesticide residues in food, on a regular basis. Because the public has no way of knowing whether these chemicals are present in their food, laws and regulatory programs are critical for protection from involuntary exposure to this potential hazard. Unfortunately numerous Congressional and government reports have suggested that these are serious inadequacies in the existing programs that regulate pesticides.[1] In particular, several of these studies specifically concluded that the current Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) programs do not adequately protect consumers from pesticides in food.

Responsibility for protecting the public from pesticide residues in food is shared primarily by the EPA and FDA. Under the FIFRA, EPA has the authority to regulate the sale and use of pesticides in the United States. FIFRA requires that all pesticides sold in the U.S. be licensed, or registered, for use by EPA. To register a pesticide, EPA must determine that the chemical will not cause "unreasonable adverse effects on the environment" or humans. In other words, that the benefits arising from the chemical's use outweigh the risks. EPA relies almost exclusively on health and safety tests conducted by the pesticide manufacturer when deciding whether to register a pesticide.

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[1] See, The Environmental Protection Agency and the Regulation of Pesticides, Senate Committee on the Judiciary, Subcommittee on Administrative Practice and Procedure, 94th Cong., 2d. Sess. (1976); Cancer-Causing Chemicals in Food, House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, 95th Cong., 2d. Sess. (1978); General Accounting Office (GA)), Delays and Unresolved Issues Plague New Pesticide Programs (1980); EPA Pesticide Regulatory Program Study, House Committee on Agriculture, Subcommittee on Department Operations, Research, and Foreign Agriculture, 97th Cong., 2d. Sess. (1982); GAO, Monitoring and Enforcing Food Safety -- An Overview of Past Studies (1983); GAO, Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks (1986); GAO, Nonagricultural Pesticides: Risks and Regulations (1986); GA, Pesticides: Better Sampling and Enforcement Needed of Imported Food (1986); and GAO, Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues (1986).

If the pesticide is to be used in the production of a food crop or animal feed, the Federal Food, Drug and Cosmetic Act (FFDCA) requires that, in addition to being registered under FIFRA, the pesticide must have a "tolerance," or maximum allowable limit, for pesticide residues, or an exemption from a tolerance. Tolerances are set for each individual crop or food type, including vegetables, fruits, eggs, meat, and processed food, on which the pesticide will be used.

In 1970, the authority for registering pesticides and establishing pesticide tolerances was transferred to EPA, from the United States Department of Agriculture (USDA) and FDA, respectively. FDA, however, retained the authority to enforce the tolerances, and to implement seizure actions and regulatory sanctions for food products in violation of the established tolerances.[2] To enforce these tolerances, FDA conducts nationwide monitoring of food for levels of pesticide residues.

A. EPA's Tolerances May Permit Unsafe Levels of Pesticides in Food

Many EPA tolerances may have been established at levels that allow unsafe, unnecessarily high amounts of pesticide residues in food. Often, tolerances are established without sufficient toxicological data to assure that the levels chosen are safe for human exposure. In some cases, when data do exist, they are inadequate, invalid, or even fabricated. Further, when developing tolerances, EPA relies on arbitrary assumptions about what constitutes an "average" diet and what safety factors should be used. Tolerances are rarely revised either when new scientific information is received about a pesticide or when a chemical is removed from the market. Inert ingredients and other chemicals of toxicological concern that may leave residues in food are not considered in tolerance setting. Finally, the presence of carcinogenic pesticides in food is permitted, even though no "safe" level of exposure to such substances may exists.

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[2] USDA is responsible for monitoring poultry and certain egg products for pesticide residues and enforcing the relevant tolerances.

1. Tolerances are Established Without Adequate Data

Tolerance calculations may prove unreliable for many pesticides now in use because the scientific data on which they are based are incomplete or invalid. These pesticide tolerances were established without information on the chemicals' potential to cause cancer, birth defects, sterility, or genetic mutations. This is because chronic health tests have only been routinely required since the early 1970s, after amendments to the FFDCA and FIFRA transferred pesticide tolerance-setting responsibility to EPA. The primary cause of these data gaps is that 600 of the 1,200 pesticide active ingredients now used were registered prior to the establishment of modern pre-market testing requirements. Congress recognized this problem and, in 1972, directed EPA to close these critical gaps in the toxicological database through a process known as reregistration. As this long overdue reregistration process slowly proceeds, more and more data gaps have surfaced. Until recently, the real magnitude of the number of pesticides registered with little or no data was not known.

EPA's progress on reregistration has been minimal to date. As of April 1986, EPA had not completed one final reregistration assessment for any of these chemicals. In the meantime, EPA allows pesticides with data gaps to continue to be used and the tolerances established without sufficient data continue to be regarded as the rule of thumb.

Currently EPA is reviewing these older chemicals, and some new ones, in its Registration Standards program. By the end of FY 1985 (September 30, 1985), EPA had completed Standards for 117 active ingredients. NRDC reviewed the contents of these Registration Standards and published this analysis in 1986 in the report, Pesticide Reregistration: An Evaluation of Progress. Each Standard is intended to set forth the conditions of continuing registration, including updated labels, submission of missing data, and reassessment of existing tolerances. However, the currently-issued standards simply illustrate, rather than remedy, serious deficiencies in existing tolerances. Only four Registration Standards identified tolerances as adequate and fully supported by necessary health and safety data. Fourteen Registration Standards revealed that the public's maximum potential exposure to the pesticide in food may exceed the amount considered safe to ingest. The chemicals and the percentages by which the calculation of maximum potential dietary residues, or Theoretical Maximum Residue Contribution, exceeds the acceptable intake as determined from toxicological tests are presented below:

Carbofuran	114%
Chlorpyrifos	331%
Demeton	129%
Dioxathion	3,600%
Disulfoton	170%
Diuron	182%
Endosulfan	140%
Ethion	258%
Ethoprop	115%
Lindane	7,883%
MCPA	600%
Methidathion	203%
Monocrotophos	132%
Phorate	1,031%

For 23 other chemicals the Registration Standards indicated that EPA had insufficient data to determine the amount of residues considered safe to ingest. Nonetheless, these chemicals are continuing to be used on food.

Although these Registration Standards provide the best insight to the inadequacies in many pesticide tolerances, there are many other food-use pesticides for which standards have not yet been issued. For these chemicals, the recent estimates of the extent of the data gaps provide a glimpse into the validity of existing tolerances. In 1982, a House Agriculture Subcommittee estimated: 79 percent of the pesticides now in use lack adequate cancer data; 90 percent lack sufficient mutagenicity data; and 60 percent lack adequate teratogenicity data.[3] In 1984, the National Academy of Sciences released the results of their investigation of data gaps.[4] The report concluded that for only ten percent of the pesticides, including both active and inert ingredients, on the market was sufficient toxicological data with which to conduct a complete health hazard assessment available. For an additional 24 percent, only a partial health hazard assessment could be derived from available data. Even EPA acknowledges that for the vast majority of pesticides widely in use, "database are woefully inadequate and the existing data have not been evaluated by current standards."[5]

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[3] EPA Pesticide Regulatory Program Study, House Committee on Agriculture, Subcommittee on Department Operations, Research, and Foreign Agriculture, 97th Cong., 2d. Sess. (1982).

[4] National Academy of Sciences, Toxicity Testing: Strategies to Determine Needs and Priorities, 1984.

Even where toxicological data do exist at EPA, the data may not be scientifically adequate to support the establishment of pesticide tolerances. In 1976, FDA investigators uncovered a major scandal at Industrial Bio-Test Laboratories (IBT) in Northbrook, Illinois. The registration of over 200 pesticides has since been found to be based to some degree on IBT data. At least 90 of the pesticides registered with invalid IBT data are intended for use on food crops. Twenty-two of these food crop pesticides had at least three invalid chronic health effects tests performed by IBT.

2. Tolerances are Based on Outdated Dietary Consumption Data

Another major flaw in EPA's tolerance-setting scheme is the use of outdated "food factors", or estimates of average dietary consumption of individual food commodities. To establish tolerances that are safe, EPA calculates dietary exposure to pesticides. EPA has assumed, for example, that no individual consumes more than 7.5 ounces per year of avocado, artichokes, melon, eggplant, or nectarines. These figures underestimate many individuals' consumption of certain foods; therefore EPA's tolerances based on these estimates do not accurately assess of the public's total exposure to pesticide residues in food. Although the food factors have recently been revised through EPA's Tolerance Assessment System (TAS), many unanswered questions exist for TAS. TAS is a computer-based system which can estimate dietary exposure to a pesticide and then compare that estimate to a previously determined acceptable dietary intake for the pesticide. TAS can estimate dietary exposure for the total U.S. population and 22 subgroups of the population. The primary benefit of TAS is the ability to estimate dietary exposure within the subgroups. EPA believes the estimated exposures will be highest in the infant and child subgroups. For example, based on 1977 consumption data, the average toddler consumes per unit of body weight, 16 more times milk products, 11 times more fresh bananas, 10 times more peanut butter, and 6 times more apples than the typical adult women. USDA consumption data from 1985 indicate that for certain foods, particularly fruits, the discrepancy between child and adult consumption is even greater. Recently, EPA conducted a dietary assessment for a hypothetical pesticide using TAS. EPA calculated that average dietary exposure to the chemical for the U.S. population constituted 54.8% of the acceptable dietary intake, or ADI; non-nursing infants and children one to six years old had estimated exposures equivalent to 138.5% and 195.7% of the ADI, respectively.[5]

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[5] Statement of John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, before the Operations, Research, and Foreign Agriculture Subcommittee, House Agriculture Committee, April 18, 1985, p.2.

TAS does not ameliorate all of the problems with current tolerance setting. It merely addresses the past deficiencies in estimating dietary exposure to pesticides. EPA is currently stating that TAS will be used for tolerances for new chemicals and for evaluating the dietary risks of chemicals in special review. The Agency has not announced any plans to revise existing tolerances with TAS. Also, TAS does not consider non-dietary exposure to pesticides, e.g., occupational or households. Therefore, EPA's tolerances are based solely on consideration of dietary exposure to pesticides even though the public may come into contact with pesticides in their drinking water, homes, or places of work.

3. Inert Ingredients of Toxicological Concern are Not Regulated

Another issue rendering EPA's tolerance-setting system ineffective is the complete failure to regulate the inert ingredients contained in pesticide products. Pesticide products contain both an active ingredient used to control the pest and an inert ingredient used principally to "carry" and maintain the stability of the active ingredient. Most commonly, the amount of the inert is substantially greater than the active. Some of these inerts are innocuous, such as molasses, corn cob grits, or salt. But in many other cases the inert is a chemical known or suspected of causing serious health risks.

EPA has systematically failed to consider the health or environmental effects of inert ingredients in regulating pesticides under the FIFRA and the FFDCA. Under FIFRA, in determining whether pesticides present any unreasonable adverse effects on man or the environment, the Agency has, as a policy, not requested submission of any chronic health and safety information for inerts. Likewise, under FFDCA EPA has granted exemptions from tolerances for more than 500 inert ingredients.

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[5] Stephen Saunders, EPA, "Briefing Paper on the Tolerance Assessment System for Presentation to the FIFRA Scientific Advisory Panel", February 1987, p. 22.

Recently, EPA reviewed the 1,200 commonly used inerts to identify these chemicals of toxicological concern. As a result, the Agency developed two lists of approximately 100 inert ingredients that present human health risks. List 1 contains inerts of toxicological concern and List 2 contains the inerts that are potentially toxic-based on structural similarities to compounds already known to be hazardous. NRDC has determined that at least 30 of these pernicious inerts have received exemptions from tolerance. However, EPA regulations state that exemption from tolerance requirements can only be granted when the "total quantity of the pesticide chemical" in the food "will involve no hazard to the public health."[7] These exempted chemicals that may be occurring as residues in dangerous amounts in our food include the carcinogens benzene, epichlorohydrin, formaldehyde, methylene chloride, and vinyl chloride. FDA recently prohibited the use of methylene chloride as an aerosol propellant in hair sprays due to its cancer risk. However, this compound is still used in food use pesticides and exempted from tolerances. GAO recently reported that EPA has little toxicology or residue data on most food use inerts. Therefore, both the toxicity and extent of public exposure to residues in food are unknown.[8]

Recently EPA announced the release of a new policy regarding inert ingredients in pesticides. EPA is not specifically planning to revoke the tolerance exemptions for toxic inerts according to this policy. Instead the Agency may revoke certain exemptions in the future when data are available to establish a tolerance. In the interim, consumers may be exposed to dietary residues of inerts exempted from tolerance even though EPA cannot say that such exposure "will involve no hazard to the public health."

4. Tolerances are Established for Carcinogens

The FFDCA prohibits the use of cancer-causing food additives.[9] However, in 1978, there were at least 940 tolerances for pesticides now believed to cause cancer.[10] In 1985, EPA identified at least 47 carcinogenic pesticides registered for use on food.[11] For these chemicals, over 1,600 tolerances have been established. This is an insupportable double-standard because there is no evidence that carcinogenic pesticide residues in food are any less dangerous to human health than carcinogenic food additives.

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[7] 40 C.F.R. Part 180.1001(a).

[8] GAO, Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks, April 1986.

[9] 21 U.S.C. § 348.

Furthermore, EPA is required by existing law to establish tolerances at "safe" levels in order to protect public health. Under the statutory mandate of the FFDCA, it is the duty of the Administrator to protect the consuming public from exposure to carcinogens and other chronic health hazards in their food supply.[12] These cases discuss in detail the intent of Congress in enacting the FFDCA and charging the federal government with the responsibility of setting "safe" levels of chemicals consumed in human food. Likewise, applicable EPA regulations provide for a "zero" tolerance for pesticide residues where "the chemical is carcinogenic to or has other alarming physiological effects upon one or more species of the test animals used, when fed in the diet of such animals."[13]

In setting tolerances, the Agency determines the maximum toxicologically permissible exposure to a pesticide by assuming that a threshold, or no observable effect level, for toxic effects exists for exposure to pesticides. However, many scientists believe that there is no such level for carcinogens

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[10] Cancer-Causing Chemicals in Food, House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, 95th Cong., 2d. Sess. (1978).

[11] John A. Moore, Assistant Administrator, EPA, letter to Congressman Henry Waxman, Attachment D, October 2, 1985.

[12] See, e.g., Environmental Defense Fund ("EDF") v. Ruckelshaus [DDT], 439 F.2d 584 (D.C. Cir. 1971); EDF v. HEW [DDT], 428 F.2d 1083 (D.C. Cir. 1970); EDF v. EPA, [heptachlor and chlordane], 548 F.2d 998, 1005 (D.C. Cir. 1976) (cert. denied 431 U.S. 925 (1977); EDF v. EPA [aldrin and dieldrin] 510 F.2d 1292, 1302 (D.C. Cir. 1975); cf., EDF v. EPA, 598 F.2d 62, 88 (D.C. Cir. 1978).

[13] 40 C.F.R. Part 180.5(b).

-- that is, any exposure to a cancer-causing agent could initiate cancer. EPA Administrator William Ruckelshaus has acknowledged the impropriety of assuming that no effect levels exist for carcinogens and stated, "the Agency is assuming a no-threshold approach for regulating carcinogens."[14] Nonetheless, EPA continues to establish tolerances that permit the presence of carcinogenic pesticides in food despite the Agency's failure to demonstrate that the residues of a carcinogenic pesticide in food are safe.

B. FDA Monitoring of Food Does Not Accurately Identify Pesticides in Food

Samples collected are analyzed for pesticide residues most commonly by a chemical test used to detect the presence of numerous pesticides simultaneously. This test is called a multiresidue scan. In 1978, a House Congressional Subcommittee sharply criticized FDA's pesticide residue monitoring techniques. The Subcommittee report pointed out that FDA's methods were unable to detect 70 percent of the tolerances established for pesticides suspected of causing cancer.[15]

Last year GAO again reported on the inadequacies of FDA's laboratory methods. Approximately 500 pesticides are registered for use on food or may leave residues in food. FDA does not regularly test for pesticides that cannot be detected by the multiresidue scan. At best, FDA's five scans can cumulatively detect approximately 40% of the pesticides that may leave residues in food. However, FDA normally only uses one scan per sample. Some of the chemicals that cannot be detected in the scans include the pesticides benomyl, daminozide, the EBDCs, paraquat, DBCP, and dinoseb. Approximately 40 percent of all pesticides classified by FDA as having a moderate to high health hazard cannot be detected by any of the five multiresidue scans.[16]

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[14] William D. Ruckelshaus, Administrator, EPA, letter to Congressman James J. Florio, November 8, 1983.

[15] Cancer-Causing Chemicals in Food, supra, note 10.

[16] GAO, Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues, October 1986.

C. FDA Enforcement Programs Are Ineffective

Under FFDCA, FDA inspectors may seize interstate shipments of food with illegal levels of pesticide residues, seek injunctions to stop further shipments of adulterated food, and initiate criminal prosecution against those responsible for the illegal residues. A "violative" sample results from either (1) outright violation of an EPA tolerance through illegal application of a pesticide (in excessive amounts or to a non-approved crop type) or (2) the absorption of banned pesticides which linger in the soil. FDA's enforcement programs suffer from the same basic problem as the Agency's monitoring efforts: the Agency has considerable responsibility, but only limited legal and financial resources to carry out these responsibilities. As the FDA Study Group aptly describes, "enforcement sanctions currently available to the Agency are not always suitable for controlling and for deterring . . . illegal chemical residues."[17]

In reality, FDA has initiated very few seizures, injunctions, or criminal prosecutions against pesticide residue violations. Historically, three percent of FDA's surveillance samples violate allowable residue limits, and seven to ten percent of the compliance, or follow-up, samples are in excess of legal residue limits.[18] For example, in 1978, FDA initiated four seizures of contaminated produce and in 1977, only one seizure was initiated, injunctions and criminal prosecutions were virtually nonexistent.[19] The GAO revisited the issue of poor FDA enforcement last year. For 60% of the pesticide violations reviewed by GAO, FDA did not remove any food from commerce, and in no cases did FDA penalize growers.[20] GAO's analysis also showed that FDA laboratories took an average 28 calendar days to complete product processing. This did not include the time needed to collect the sample and take action to seize violative products.[21]

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[17] FDA, Study Group on FDA Residue Programs, FDA Monitoring Programs for Pesticides and Industrial Chemical Residues in Food, June 1979.

[18] Id., p. 65.

[19] Id.

[20] Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues, supra, note 16.

D. EBDCs

The EBDC family of pesticides illustrate many of the deficiencies in the federal regulatory programs discussed above. For example, many pesticides are used frequently on food, but because the chemical cannot be detected by FDA's routine laboratory methods, we have very little information about the presence of these chemicals in the food. The ethylenebisdithiocarbamates, or EBDCs (six different chemicals) are the most widely used group of fungicides in the United States, constituting approximately 22 percent of all fungicides used in American agriculture, and 57 percent of total fungicides used worldwide. EBDCs are extensively on wheat, potatoes, citrus, tomatoes, apples and other crops. However, only minimal data exist to determine the frequency and levels of EBDCs residues in food because FDA cannot routinely detect these chemicals.

Both through environmental degradation and through the application of heat in processing or cooking, the EBDCs are known to break down into ethylenethiourea (ETU), a known carcinogen. In six separate cancer studies, ETU and the EBDCs were shown to cause liver, lung and thyroid tumors. EPA documents also show that the EBDCs and ETU may cause birth defects and genetic mutations. EPA's decision documents indicate a lifetime dietary cancer risk up to 4.9×10^{-4} (1 cancer per 2,000 exposed or roughly 100,000 additional cancers in the general population) and occupational cancer risk as high as 1.1×10^{-2}. The NAS report has estimated up to 400,000 additional cancer cases resulting from dietary exposure to four of the EBDCs (zineb, maneb, mancozeb, and metiram).

EPA documents state that the "entire US population is potentially subject to dietary exposure to ETU". This document also cites a duPont study of ETU in processed foods (e.g., canned vegetables and fruits) which found 23 percent of the sample to be contaminated. ETU has tainted food for which no tolerances exist, such as meat, milk and eggs, and has also been found in drinking water. Despite the significant health hazard of ETU, EPA has no tolerance or legal residue limit for the compound; EBDCs tolerances are not allowing only safe residue levels because they do cover ETU. Furthermore, by statutory definition, any detectable amount of the compound renders food "adulterated" and required FDA to seize the food in order to protect consumers. In addition to the general dietary hazard posed by the EBDCs and ETU, 60,000 applicators are at risk. The EPA Decision Document notes that ETU has been found in applicators' urine.

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[21] GAO, Food and Drug Administration: Laboratory Analysis of Product Samples Needs to be More Timely, September 1986.

EPA placed these chemicals into RPAR (an intensive EPA review) in 1977 because of concerns about its carcinogenicity and the formation of the breakdown product ETU which is carcinogenic and teratogenic. Following five private meetings with the registrant (duPont and Rohm & Haas) which were provided with advance opportunity to review EPA's Decision Document, the RPAR was terminated and the chemical returned to registration with label changes only.

On January 3, 1985, the California Department of Food and Agriculture commenced reevaluation of all products containing the EBDCs registered for use in California because of concerns about the oncogenicity of these compounds and the oncogenicity and teratogenicity of ETU.

In addition, California chemists found available methods of analysis for EBDC and ETU to be cumbersome, time consuming and of questionable accuracy. The California Department of Food and Agriculture (CDFA) determined them to be unacceptable for measuring the amounts of residue of either EBDC or ETU on treated crops. The lack of an accurate method to analyze for residues and the risk estimates of a cancer hazard raised sufficient concerns to place the EBDCs into reevaluation.

The Department in cooperation with the registrant has been working to develop an adequate analytical method of residue analysis for EBDC and ETU. By January, 1986, no acceptable analytical method of analysis has been developed. The Department has written to the EPA to inform them of its concerns and to summarize its efforts over the last few months to develop an acceptable methodology of residue analysis. EPA disagrees with CDFA and believes that the existing method -- though cumbersome and time-consuming -- can be accurate. However, such a method may not be suitable for enforcement purposes which requires rapid results to allow timely seizures of illegally contaminated food.

In 1983, NRDC and the AFL-CIO filed suit against EPA for its practice of holding closed meetings with pesticide registrants concerning the regulation of their products. As part of the 1984 settlement of this litigation, EPA agreed to formally reassess previous decisions on chemicals that were improperly reached through closed-door meetings. Among the chemicals to undergo reassessment were the EBDCs that EPA had removed from special review after meetings with the registrants. EPA agreed to complete this review by December 31, 1986. On December 30, 1986, EPA requested an extension for the EBDCs reassessment until March 30, 1990 -- over three years beyond the originally required completion date. In a December 30, 1986, letter to NRDC, EPA stated that it still "lacks much of this necessary data" for completing the EBDCs risk assessment. The main reason presented by EPA for furthering delaying this decision is that adequate data on the presence of the EBDCs and ETU in food are still not available and will need to be developed in the future. Pending further testing, these chemicals, known to be hazardous, are still being widely used on food, but FDA does not routinely test for their presence in food and EPA is not prepared to take regulatory action for another three years.

III. NAS REPORT MAY UNDERSTATE RISK FROM CANCER-CAUSING PESTICIDES IN FOOD

The NAS report estimates that over our lifetimes the presence of 28 carcinogenic pesticides applied to food may cause 1.46 million additional cancers in the U.S. population. Some critics will charge that the NAS calculations overstate the risk from carcinogenic pesticide residues in food because NAS assumed that pesticide residues occurred at tolerance levels. However, these numbers many underestimate the risk for several reasons.

First, pesticide residues occasionally are higher than established tolerances. According to recent GAO reports, approximately 2-4 percent of the foods sampled by FDA contained pesticide residues that exceed tolerance levels. The violation rate may be even higher because FDA's routine laboratory methods can only detect about half the pesticide chemicals that may leave residues in food.

Second, NAS estimated the cancer risk posed by only 28 food use pesticides. The total number of carcinogens in our food supply is far greater than 28. EPA has already identified additional carcinogens and many more will be discovered as chemicals are finally tested. In fact, the NAS report identifies an additional 27 cancer-causing pesticides used on food that were not included in the risk estimates. The NAS report contains an estimate of the carcinogenic risk solely from the plant growth regulator daminozide of 8.3×10^{-3} excess cancer cases. This chemical was not included in the total risk estimate but it alone poses a larger risk than all the other 28 carcinogens combined. Another one of the excluded chemicals, asulam, is a more potent carcinogen than 19 of the carcinogens NAS included in its risk assessment. This chemical is not considered because it was not an herbicide, insecticide, or fungicide. The NAS report also did not calculate the risk from two major use herbicides, atrazine and 2,4-D, that are carcinogenic. These chemicals were not listed as carcinogens because EPA received positive cancer data too late for incorporation in the report.

The majority of pesticides in use today have never been thoroughly tested for their health hazards. Many have never been tested to determine whether they cause cancer. Currently, no complete statistics exist for fully identifying the data gap for cancer testing. In 1982, a House Subcommittee estimated that between 79 and 85 percent of pesticides had not been adequately tested for carcinogenicity. By the end of Fiscal Year 1985, EPA had issued registration standards for 115 pesticide active ingredients: 36 percent of these chemicals had no acceptable oncogenicity studies on file at EPA; 41 percent had some data but had not completely fulfilled the requirement (generally for two tests); and only 23 percent had all required cancer data. More recently, the California Department of Food and Agriculture has initiated a program to identify the data gaps in chronic testing for all pesticides used in California and require the submission of those tests. In the first phase of this program, the Department is closely examining the 200 pesticides used in California in the greatest amounts. Of these 200, 50 pesticides do not have any cancer data on file with the Department. Only 50 pesticides have fully satisfied the cancer testing requirements. The remaining 100 ingredients have inadequate or insufficient cancer data on file.

Third, the NAS report understates the risk of cancer from pesticides in our food because only active ingredients were examined. Pesticide products contain both active and inert ingredients. Inert ingredients are just as likely to leave residues in food as active ingredients. EPA recently identified 55 hazardous inerts. Fifteen of these are carcinogens used on food. These inerts are listed below.

Benzene
Carbon tetrachloride
Chlorobenzene
Chloroform
Dioxane
Ethylene dichloride
Formaldehyde
Hydrazine
Isophorone
Methylene chloride
Perchloroethylene
o-Phenylphenol
Propylene oxide
Rhodamine B
1,1,1-trichloroethane
(methyl chloroform)

Also the report did not examine the risks posed by degradation products of contaminants of pesticides that are carcinogens. For example, nitrosamines, hexachlorobenzene, epichlorhydrin, and dioxins occur as contaminants in certain pesticides and are carcinogens. The pesticide captan has a metabolite THPI that EPA is concerned may also be a carcinogen.

Fourth, the NAS report did not consider all the dietary risks posed by carcinogenic pesticides. Some of these chemicals have contaminated drinking water. For example, alachlor has been found in both surface and ground waters that are drinking water supplies. Atrazine has also been detected in drinking water. EPA has also identified approximately 60 pesticides that have the potential to contaminate ground water. Some of these are carcinogens.

Fifth, the NAS report may understate the risk because it does not consider the possible synergism, or enhanced carcinogenicity, that can occur from simultaneous exposure to pesticides. Also some of the computer models used to develop the potency factors for carcinogens by extrapolation from animal studies may not be sufficiently conservative.

Finally, in developing the cancer risk estimate, NAS used mean estimates of food consumption. In other words, even though the more up-to-date Tolerance Assessment System -- with its capacity to estimate dietary consumption patterns for 22 subgroups of the U.S. population -- was used, NAS based the calculations on an average dietary consumption for the entire population. Certain subgroups of the population will be at greater risk from carcinogenic pesticide residues because they consume greater amounts of the foods containing these residues. For example, according to TAS, toddlers ingest 16 times more milk products, 11 times more fresh bananas, 10 times more peanut butter, and 6 times more apples than adult women.

IV. REFORMS NECESSARY TO PROTECT THE PUBLIC FROM CANCER-CAUSING PESTICIDES IN FOOD

The NAS report has clearly illustrated the risks posed by pesticides in food and the devastating consequences of the government's weaknesses in the federal government's programs to regulate pesticides. Although some organizations will wish to debate the report's findings, such an exercise would be thoroughly unproductive. The cancer cases estimated to result from dietary exposure to a handful of carcinogens may be avoidable. Measures can be immediately taken to reduce the risks these cancer-causing chemicals pose to consumers. Also amendments to the federal pesticide law will prevent this dire situation from continuing.

NAS has estimated a significant number of potentially-available cancer cases that may occur from residues of only 28 pesticides in food. In fact, twelve of these 28 pesticides present 96 percent of the cancer risk. These chemicals are: linuron, zineb, captafol, captan, maneb, permethrin, mancozeb, folpet, chlordimeform, chlorothalonil, metiram, and benomyl. We recommend that EPA cancel the use of these chemicals on food immediately. Removing these chemicals would substantially reduce the carcinogenic risk posed by pesticides in food.

Another tool currently available to EPA to reduce the risk from carcinogenic pesticides in food is the Delaney clause of the FFDCA. The NAS report estimates that the risk from carcinogenic pesticides in food could also be reduced by approximately 55 percent if the Delaney clause of the FFDCA was applied to pesticide residues that occur in processed food. We recommend that EPA immediately implement the Delaney clause as it applies to pesticides in processed foods, and revoke all Section 409 tolerances for pesticides that concentrate in processed food. Any Section 409 tolerances for oncogenic pesticides that concentrate in processed food are now in violation of the FFDCA.

Beyond these measures that EPA can now take, reform of the federal pesticide law will ensure the public is truly protected from the dangers of pesticides in food. Last year legislation was introduced in both the Senate and the House that would have substantially improved EPA's regulation of pesticides. In the final hours of the last session of Congress, this legislation was not enacted largely because of misguided efforts to preempt state regulation of pesticides in food and to eliminate pesticide users' liability for damages caused by these chemicals, such as ground water contamination. We urge this Committee to renew its efforts to amend FIFRA rapidly. Last year's Senate bill is an important starting point for reform legislation.

Some legislative reforms would specifically reduce the substantial risks from carcinogenic pesticides in food uncovered by the NAS report. These include requiring full health and safety testing for pesticides, expediting EPA's procedures for taking dangerous chemicals off the market, requiring regulation of hazardous inert ingredients, and requiring the substitution of noncarcinogenic pesticides for carcinogenic pesticides used in food.

The fundamental deficiency in the current pesticide regulatory scheme is the absence of valid scientific data addressing the health hazards posed by the 2.6 billion pounds of pesticides used annually in the U.S. Last year's legislation established a mandatory schedule (with deadlines) for obtaining the full health and safety testing of pesticides. This must be a component of any serious reform legislation. We would also recommend that legislation include a fee on each active ingredient to be paid by pesticide registrants that will provide the financial resources necessary for EPA to complete reregistration in a timely fashion. EPA should not reregister a pesticide until all tolerances have been reassessed and revised as needed to comply with the requirements of the FFDCA. According to Section 408, tolerances should only permit safe levels of pesticides in food.

EPA has now identified approximately 120 known and potentially hazardous inerts used in pesticide products, but has taken virtually no action to restrict the continued use of these chemicals. Current law does not even provide for the identification of these inerts on product labels. Last year's Senate bill would have established clear EPA authority to regulate inerts and created an appropriate regime for accomplishing that result. EPA would have developed a priority list of inerts targeted for regulation -- including those requiring additional health and safety testing and identification of inerts on the label. FIFRA must be amended to prevent hazardous inerts from posing unregulated risks to the public.

In the past, EPA's efforts to take dangerous chemicals off the market have dragged on for years. For example, captan, one of the carcinogens NAS included in its report has been in EPA's special review process since 1980. Even though the Agency has been concerned about the carcinogenicity of this compound and particularly its presence in food, EPA has not imposed any regulatory measures to protect the public from this chemical. Last year's legislation would have significantly streamlined EPA's process for both cancellation in several respects. The legislation would have limited the time for special review and cancellation hearings. FIFRA must be amended to expedite EPA's procedures for removing hazardous pesticides from use.

Finally, in order to truly protect the public from the hazards of pesticides, nonhazardous pesticides should replace the use of dangerous chemicals. For example, the uses of carcinogenic pesticides should be replaced by noncarcinogenic compounds. We recommend that this Committee consider amending FIFRA to require specifically the substitution of noncarcinogenic pesticides for carcinogenic chemicals. Where noncarcinogenic alternatives do not exist, legislative reform is necessary to encourage the rapid registration of safe substitutes.

The **CHAIRMAN**. Thank you.

Let me first ask this question of Dr. Heldman.

I have been told, and you can tell me if I am correct in this, that some segments of the food industry have told their suppliers that they would not accept foods treated with pesticides in special review.

Has NFPA or any of its members taken such a position?

Dr. **HELDMAN**. Not that I am aware of.

The **CHAIRMAN**. Are you aware of any segments of the food industry doing that?

Dr. **HELDMAN**. I am aware of certain States where there has been State action taken to set a tolerance different from the Federal, in which companies have been responded, and said they would prefer not to use those particular raw materials.

The **CHAIRMAN**. But this was action taken by the industry itself, not State action?

Dr. **HELDMAN**. It was in response to a State action.

The **CHAIRMAN**. I'm confused. Were they doing something that they were required to do or something voluntary?

Dr. **HELDMAN**. No; voluntary. Voluntary in that situation.

The **CHAIRMAN**. You state that residues are below tolerance for most foods, is that correct?

Dr. **HELDMAN**. Correct. This is in processed foods. And that's the industry we represent.

The **CHAIRMAN**. The FDA said they inspect a little less than 1 percent of our food supply.

How do we determine that these residues are below tolerances?

Dr. **HELDMAN**. Well, as a result of the report, our industry obviously was interested in getting a fair assessment and picture of the situation. So, within the past couple of weeks, our association has been active in assembling data, actual residue data on processed foods.

We were able to, in a relatively short period of time, collect information representing some 10,269 samples of processed foods which have been analyzed for somewhere between 200 and 300 pesticides, and 99 percent of those samples showed nondetectable levels of the residue.

The **CHAIRMAN**. Let me ask you and Ms. Mott this question because as people hear of this, they become concerned about it. Everyone will talk about how, reading the report, they became very concerned. About 1 out of 50 people may say they have read it well, but all will certainly read the press accounts which will vary depending upon how much attention the paper gives it as a whole, or on what particular part. I don't mean this as a criticism of the press. Various media persons will look at various parts, depending upon their market, the type of news media, the audience they are aiming for, and what their editors want them to pick up on.

So I want to ask Ms. Mott and yourself the same question because consumers have to know what they are going to do in response to this report. You first, sir.

How serious is the problem presented by the National Academy of Sciences?

Dr. **HELDMAN**. Well, we feel that the concern is one of public perception. How is this information going to be shared with the public? If it is presented in a form, which it could be, as indicated by the tables, we feel that the perception is going to be unfair, and would represent a concern that we have to respond to in some way.

We feel that we can respond to that by sharing more information of the data. I indicated this morning that the actual levels are anywhere from 100 to 1,000 times lower than tolerance, and that would lower those risk values that are presented in the report by that same magnitude.

The CHAIRMAN. Ms. Mott, same question.

Ms. MOTT. I think it would be an absolute waste of time if there was considerable debate about whether these risks are way too high. I think the real issue, and this is the issue that consumers should remember, that we have startling evidence that the Federal programs that are charged with protecting the food supply are not doing their job.

What I would tell all consumers to do is write their Senators and write their Representatives and say it is time to reform the Federal Pesticide Law. We came very close last year. I think that provides important momentum that we can use, and I think this year we should try and succeed in enacting reforms to FIFRA.

Mr. MEYERHOFF. Mr. Chairman, could I add one point to that?

The CHAIRMAN. Certainly.

Mr. MEYERHOFF. We have heard a lot this morning about the fact that we don't know the precise amount of residues in our food of these 28 carcinogens. According to NAS, they may pose a cancer risk of 1.45 million cancers for this generation. That's just for 28 chemicals.

There are roughly 300 pesticides used in the American food supply. The overwhelming majority of those haven't been adequately tested for cancer. The NAS report, as our press release accurately reflects, assumes that 60 percent of the herbicides used, 30 percent of the insecticides and 90 percent of the fungicides, when tested, will be shown to be carcinogenic.

We are talking about a very large number of likely carcinogens that are being used in food. And we have a Federal regulatory system that has been fatally flawed. This report is one of a series of reports by this and other congressional committees, by the GAO, by the NAS in the past, and others. They have all documented that the current law is a charade, that it doesn't protect the food, and that EPA is not doing its job.

The CHAIRMAN. Mr. Dunkelberger, do you want to add anything to this, sir?

Mr. DUNKELBERGER. As Dr. Heldman made clear in his testimony, the food processing industry is, in essence, the customer of the companies that make the pesticides, and recipient of the pesticides that are lawfully approved by EPA. So we have little or no control over that element of the process.

Where we do have control is determining how the pesticides will be used on the crops that are grown for processing. Dr. Heldman's formal statement has outlined a number of the steps that are taken by food processors to assure that all pesticides are used lawfully, to assure that they are not used unnecessarily, and to assure, once they are used, the pesticides are very substantially reduced, such that the eventual residues in the finished product are either nonexistent, or at such a low level as to be totally unrelated to any theoretical assumption of risk.

To the extent that anyone draws the assumption from the NAS Report, or from any comments by witnesses on it, that there is any significant safety concern or should be any safety concern for processed foods, that assumption is totally unfounded. The fact is that processed foods have extremely low levels of pesticides and that the food supply is safe as presented to the American consumers. We frankly are more than willing to participate in any consideration of revisions to FIFRA or the Food and Drug Act that may be proposed by the NAS, yourself, the NRDC, or others.

We are not saying that everything is just perfect. On the other hand, we see nothing in the regulatory scheme to create anything like a safety concern for the food supply.

The CHAIRMAN. I would note that in regard to this hearing and the one we had a week or so ago, on April 29, as to the inquiries made from my office, I should indicate again that I want as much input from all the people involved in this, whether it is the manufacturers, the processors, the suppliers, environmentalists, consumers, because we all have a stake in this.

We will also hear from the Federal and State governments. The best bill we can have is one that reflects a strong consensus of the concerns of the groups. It is also, from a pragmatic, political point of view, about the only kind that will pass.

I am also committed, as I said before, to having FIFRA legislation that reflects the changes we have seen, scientifically and otherwise, since the last rewrite, and one that corrects, at least in my mind, the lack of attention given by some of our governmental agencies. I do not mean this as a criticism of those testifying today, but I am pointing out a lack of attention that has been mandated by a lack of resources.

Let me just close with this one question, and then I want to yield to Senator Pryor. Again, I will ask you, Ms. Mott, and Dr. Heldman the same question.

Is there more we can do to assure ourselves that the public is protected and if so, what?

Ms. MOTT. Our prepared statement contains several recommendations. To just recap briefly, one of the fundamental problems facing EPA, in terms of their regulation of pesticides is, as Mr. Meyerhoff discussed, the extensive data gap.

One thing that would help prevent risks, such as the ones discussed in the NAS study, actually coming to pass in the human population for additional chemicals would be to require the rapid cancer testing and other chronic health effects testing of all pesticides, and have EPA rapidly incorporate that data into their regulatory positions on the chemical.

The other issue that I think would help EPA's regulation is that the point brought up by the EBDC example, in cases it has taken 7 to 10 years for EPA to come to a decision about whether a chemical should remain on or off the market. If EPA's procedures for reviewing hazardous pesticides were substantially expedited and they could remove dangerous chemicals from the market, the risks to consumers from these chemicals in the food supply would be substantially reduced.

The CHAIRMAN. Dr. Heldman.

Dr. HELDMAN. We would support additional funding for EPA but probably for different reasons.

If risk assessment is to be the tool that is going to be used, we feel that that tool must be used properly and with appropriate inputs. We as an association representing the food industry would be very interested in supporting them in those efforts.

The CHAIRMAN. Senator Pryor.

Senator PRYOR. Mr. Chairman, thank you.

The CHAIRMAN. Incidently, Senator Pryor, if you would yield for just a moment, one of the things that I have enjoyed, as I know you and others have, is the fact each Senator has the opportunity to have interns in the offices.

Today I have two here, Susan and Herb Gallagher, who have been sitting here patiently throughout the hearing. I just wanted to note the ability of the Gallaghers, who have a lot more energy than I do, to sit through these.

I yield back to you, Senator Pryor.

Senator PRYOR. Thanks, Pat.

Mr. Chairman, I think that I owe an apology to these witnesses here this morning, and I want to apologize because I think an hour or so ago in my remarks, maybe through the inflection or emphasizing something wrong, I left the impression that, I was a little denigrating to your organization and to the council you represent. I want to apologize for that.

Also I want to apologize if I left the impression that in any way I felt that you did not have the right to speak or to come to this hearing and state what you think is wrong with this report. I hope you will accept that apology.

Ms. MOTT. I will accept that.

Mr. MEYERHOFF. Senator, does that mean that we get invited to the tomato parade?

Senator PRYOR. Yes, you can enter the tomato eating contest. [Laughter.]

Mr. MEYERHOFF. An assumption of the risk.

The CHAIRMAN. Only if you also go to Senator Daschle's chip throwing contest.

Senator PRYOR. Well, Mr. Chairman, I do want to say that this organization represented so capably here today has stated that the National Academy of Sciences' report is understated. Is that correct?

Ms. MOTT. I said it probably understates.

Senator PRYOR. Probably.

Ms. MOTT. Because there are additional pesticides in the food supply that will subsequently be found to be carcinogenic that were not included in this assessment.

Senator PRYOR. I am concerned about your statement because your written statement, your press release, in about 6 or 7 paragraphs, attempts to capsule a very, very complex report that the chairman of the committee and the distinguished members of the panel who preceded you here, could really not capsule in a very short time. I think that is why I did not know about the meeting last night and I did not know about the press conference they held today, but it appears to me that they are really trying to get a message out.

I would like to ask if they did understate. Why do you think they did? Why is it necessary for a distinguished group like this to understate or not to level with us on all the facts that they found?

Ms. MOTT. Well, let me first say that I do not in any way mean to denigrate the august members of the committee who served on the NAS panel that developed this report. It is a truly impressive report, and I spent all last night reading the report, not once but twice. And it is full of facts and figures and valuable information that will take a long time to digest.

But our organization has been looking at the issue of pesticides in food for over 5 years now. And I think that when you look at this report in the context of my own limited study of the issue in the last 5 years, and the reports going back 5, 10 years, and even before that, you realize that what the report is again saying is that the Federal system that is supposed to be regulating and protecting consumers is not doing a good job.

Whether these numbers are too high or, in my belief, probably a little bit low, maybe way too low, it may not be necessary to spend a lot of time trying to figure out whether we can improve the numbers.

I think we should really focus on ways to reform the Federal system that regulates food.

Mr. MEYERHOFF. The NAS—2 years ago—released another report, and that report found that for only 10 percent of the pesticides used on food is there enough data to determine if they cause cancer.

This report may have understated the problem of carcinogenic pesticides in food because NAS can only look at pesticides with adequate data. It is not an intentional understatement. They only could look at those 10 percent. What about the other 90 percent?

Senator PRYOR. Well, once again, I think we are trying to put everything this morning, I know the chairman is, in perspective. If there is an alleged understatement, I want us to be very cautious also about an overstatement in response to this, because we are walking on some very, very serious ground.

Mr. Chairman, I have a suggestion, and I have worked with many areas over the years in this whole issue of pesticides, and in these areas that we are talking about this morning embodied in this report.

I may be wrong, but I have a sense that people who are involved in this never talk to each other. Am I wrong? I think you come to committees and you talk to each other. You may go on television and talk to each other. It is kind of like Gorbachev and Reagan. They never talk to each other except through channels, TV, and newspapers.

Do you all ever sit down and say, "Okay, let's take a weekend off and examine this problem and see what we can do about it?" Does that ever occur?

Mr. MEYERHOFF. Senator, last year we appeared before this committee together with representatives of the National Agricultural Chemicals Association, the chemical industry that produces these products. Before that hearing we had sat down with industry for a year, more than a year, and we reached agreement on a comprehensive rewrite of FIFRA, of the law. If that bill had passed, many of the problems identified in this report would have been addressed. For example, it would have mandated EPA to make these pesticide regulator decisions in no more than 2 years, not 10, and it would have required full testing of these chemicals so we would know the true cancer risk in the food supply.

That bill passed both the House and the Senate. Unfortunately, it became ensnarled in other issues involving the preemption of the States to protect the food.

Senator PRYOR. Was that bill supported by you and the industry so to speak?

Mr. MEYERHOFF. That's correct, and the American Farm Bureau as well.

Senator PRYOR. Is this the legislation that you still support?

Mr. MEYERHOFF. A bill was introduced, I believe last night, in the House that reflects that agreement, but also contains unacceptable preemption language and other controversial amendments. We believe that it is a very important starting point for getting a bill through the Congress this year.

Senator PRYOR. Will this solve the problems that we are addressing today? We have talked about a lot of the problems. We have talked really about very few solutions today. And I think we are at the point now where we need some solutions.

Mr. MEYERHOFF. In the short term, getting data on the chemicals, getting the carcinogens out of the food supply is the first priority. In the long term, it is critical that we be find alternatives to these chemicals, nonchemical alternatives, so we can really reduce the risk.

Dr. HELDMAN. I guess I would respond to the question by indicating that our association and our industry is willing to work with any committee, talk to any committee, work with any group in coming to a reasonable solution to the issues that we have been discussing this morning.

Mr. DUNKELBERGER. If I might add, we did indeed support the legislation that has been referred to, but we did have considerable concern with one aspect of it. That was the issue that turned out to be quite controversial—the issue of uniformity.

We are satisfied that the way to resolve these issues is right here in this committee, in this Congress, in this Government, not in 50 States. And we are satisfied that the States could do an excellent job of monitoring, of enforcement and the like. It is not in the public's interest, not in the consumer's interest, and not in the interest of anyone who seriously considered the issue to contemplate separate, disparate regulation among the States. And that is one of the issues that proved to be quite thorny in that legislation. We tend to believe if you work on finding a correct solution to the pesticide regulation and the food supply, the correct solution should be the one that resides right here in Washington with the Federal Government.

Mr. MEYERHOFF. I don't know if you want to debate on that issue now, but we would just point out that the EBDC example that has been discussed here is the EPA record, 10 years of not getting a powerful carcinogen out of food with a cancer risk of 1 in 1,000.

When EPA failed so badly to take away the power of the States, to us it is a misguided policy.

Mr. DUNKELBERGER. I guess you are right. This is not the place to debate it. But if there is a concern with the level of activity of the Federal Government, then it seems to me that the solution should be in the direction of going to the Federal Government, as you did in your litigation and elsewhere.

We think that the States can speak up, the States can participate in the registration proceedings. They can participate in these hearings. All we are saying is we don't think it is appropriate for the States to adopt their own rules regulating food products moving across State lines in interstate commerce.

As we said in another context, we don't think you should balkanize the regulation of food products containing the necessary pesticide residues.

Senator PRYOR. Mr. Chairman, I know we have a vote on the floor. My observation this morning is, even though you and I are lawyers, and I am really just a shade tree lawyer, as we used to say, probably at this moment, and on this issue, we have too many lawyers in the Senate and too few scientists. We really do not have a scientific background to deal with some of these issues. I think that is part of our dilemma and we have to rely on the best information that we get at the time.

I certainly thank you, and thank you, Mr. Chairman.

The CHAIRMAN. Thank you. And I will also say that the distinguished Senator from Arkansas has made a very good point about those who have testified here today, and others who are interested in this.

You talk about whether we should or should not debate this issue here today, and that kind of debate among yourselves would be very beneficial to all.

Have you ever reached that point where you decide you can accomplish something through conference, and you retreat to a neutral place, having gone through the metal detectors, all weapons checked at the door? I will be very, very happy to volunteer the top people of the Senate Agriculture Committee staff to conference with you at that time.

And with that, we will stand in recess, subject to the call of the Chair.

I thank you all very much.

[Whereupon, at 1:08 p.m., the committee recessed, to reconvene at 10:15 a.m., in room SD-562, Senate Dirksen Office Building, Thursday, July 30, 1987.]

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